Contains Nonbinding Recommendations

Refuse to Accept Policy for 510(k)s

Guidance for Industry and Food and Drug Administration Staff

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As of October 1, 2015, this document supersedes "Food and Drug Administration's Refuse to Accept Policy for 510(k)s," dated December 31, 2012, "Premarket Notification (510(k)) Refuse to Accept Policy," dated June 30, 1993, and "510(k) Refuse to Accept Procedures (K94-1) blue book memo", dated May 20, 1994.

For questions regarding this document, contact the 510(k) Staff at 301-796-5640. For questions regarding submissions to the Center for Biologics Evaluation and Research (CBER), contact CBER's Office of Communication, Outreach and Development at 1-800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to http://www.regulations.gov. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Identify all comments with the docket number FDA-2012-D-0523. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the guidance. Please use the document number 1793 to identify the guidance you are requesting.

Additional copies of this guidance document are also available from the Center for Biologics Evaluation and Research (CBER) by written request, Office of Communication, Outreach and Development (HFM-40), 10903 New Hampshire Avenue, WO71, Room 3128, Silver Spring, MD 20993 , by telephone, 1-800-835-4709 or 240-402-8010 , by email, ocod@fda.hhs.gov, or from the Internet at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.

Refuse to Accept Policy for 510(k)s

Guidance for Industry and Food and Drug Administration Staff

This guidance represents current thinking of the Food and Drug Administration (FDA or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for implementing this guidance as listed on the title page.

I. Purpose

The purpose of this document is to explain the procedures and criteria FDA intends to use in assessing whether a 510(k) submission meets a minimum threshold of acceptability and should be accepted for substantive review.

This guidance document supersedes three existing guidance documents titled "Refuse to Accept Policy for 510(k)s" issued on December 31, 2012; "Center for Devices and Radiological Health's Premarket Notification (510(k)) Refuse to Accept Policy" issued on June 30, 1993; and "510(k) Refuse to Accept Procedures, 510(k) Memorandum K94-1" issued on May 20, 1994.

Focusing FDA's review resources on complete submissions will provide a more efficient approach to ensuring that safe and effective medical devices reach patients as quickly as possible. Moreover, with the enactment of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), the Medical Device User Fee Amendments of 2007 (MDUFA II) and the Medical Device User Fee Amendments of 2012 (MDUFA III),[1] FDA agreed to performance goals based on the timeliness of reviews. Acceptance review therefore takes on additional importance in both encouraging quality submissions from submitters of 510(k) notifications and allowing FDA to appropriately concentrate resources on complete submissions.

Therefore, the current 510(k) Refuse to Accept (RTA) policy includes an early review against specific acceptance criteria and to inform the submitter within the first 15 calendar days after receipt of the submission if the submission is administratively complete, or if not,

[1] See Title II of the Food and Drug Administration Safety and Innovation Act (FDASIA) (P.L. 112-144), amending sections 737, 738, and 738A of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

to identify the missing element(s). In order to enhance the consistency of our acceptance decisions and to help submitters better understand the types of information FDA needs to conduct a substantive review, this guidance, including the checklists included in the appendices, clarify the necessary elements and contents of a complete 510(k) submission. The process we outline is applicable to all devices reviewed through the 510(k) notification process and has been compiled into checklists for use by FDA review staff.

It is critical to distinguish between the completeness of the regulatory submission, and the quality of the data provided and any studies conducted in support of the submission. The assessment of the completeness of the 510(k) occurs during the acceptance review, while the assessment of the quality of the submitted information occurs during the substantive review. FDA will base acceptance on the objective criteria outlined in the associated Acceptance Checklist and not on the quality of the data.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance documents describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance documents means that something is suggested or recommended, but not required.

II. Background

The purpose of the 510(k) acceptance review is to assess whether a submission is administratively complete, in that it includes all of the information necessary for FDA to conduct a substantive review and to reach a determination regarding substantial equivalence under section 513(i) of the FD&C Act, 21 U.S.C. § 360c(i). To find a device substantially equivalent under section 513(i) of the FD&C Act, FDA must find that it has the same intended use as the predicate device, and either (1) has the same technological characteristics as the predicate device, or (2) has different technological characteristics, as defined at section 513(i)(1)(B), and the submission contains information, including appropriate clinical or scientific data if necessary, that demonstrates the device is as safe and effective as the predicate and does not raise different questions of safety and effectiveness than the predicate.

The 510(k) regulations at 21 CFR 807.87 to 807.100 provide greater detail regarding the specific information that each premarket notification submission must contain. For example, the submission must include proposed labeling (807.87(e)), a statement regarding the similarities
and differences between the device and others of comparable type (807.87(f)), supporting data (807.87(f) and 807.100(b)(2)(ii)(B)), and FDA may request any additional information necessary to determine whether the device is substantially equivalent when the information provided is insufficient to enable such a determination (807.87(l)). Please also refer to our guidance document entitled, "Format for Traditional and Abbreviated 510(k)s" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm0
84365.htm).

Prior guidances and checklists relating to 510(k) RTA policy (i.e., 510(k) Refuse to Accept Policy, dated June 30, 1993, and 510(k) Refuse to Accept Procedures (K94-1) blue book memo, dated May 20, 1994) focused on defining broad issues or principles. Additionally, the checklists associated with these guidances dealt largely with administrative elements but did not address specific content that is essential for 510(k) review. As a result, FDA had accepted many inadequate submissions for review, and FDA staff invested significant time in constructing extensive letters requesting all of the additional information needed to conduct a substantive review. This approach was an inefficient use of resources and frequently lengthened review times. For additional information see CDRH's "Analysis Of Premarket Review Times Under The 510(k) Program" (http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM263386.pdf).

The goal of the guidance titled "Refuse to Accept Policy for 510(k)s," dated December 31, 2012 was to clarify the content needed in traditional, special, and abbreviated 510(k) submissions to allow FDA to conduct a substantive review, thereby enhancing the quality of received 510(k) submissions and improving overall review time. The review process presented in this document is captured in the updated Acceptance Checklists for traditional, special, and abbreviated 510(k) submissions, which FDA staff will use during the acceptance review process.

III. Scope

The information presented in this document is intended to provide FDA staff with a clear, consistent approach for acceptance review for traditional, special, and abbreviated 510(k) notifications and to outline the RTA policy on 510(k)s.

The acceptance policy does not alter the substantial equivalence decision-making process once the submission has been accepted for review; however, it does alter the start of the FDA review clock for purposes of MDUFA performance goals for those submissions that are not accepted for review. For those submissions accepted during the initial acceptance review (i.e., within the first 15 calendar days of receipt of the submission), the FDA review clock start date is the date of receipt.

This document does not address the monetary aspects or the MDUFA goals associated with 510(k)s. Information pertaining to the fees and payment procedures for submission of a 510(k) notification can be found in FDA's "Guidance for Industry and Food and Drug Administration Staff – User Fees and Refunds for Premarket Notification Submissions (510(k)s)" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM345931.pdf)

IV. Pre-submission Interaction

For general information regarding the 510(k) regulations under 21 CFR Part 807, submitters should consult CDRH's Division of Industry and Consumer Education (DICE) or CBER's Manufacturers Assistance and Technical Training Branch. Before submitting a 510(k) notification, we encourage submitters, especially those who are less familiar with the 510(k) review program or who have novel issues to address, to interact with the appropriate FDA review staff. Such pre-submission interaction is an important way of improving the quality and completeness of a 510(k). For additional information regarding the Pre-Submission process, please refer to the guidance titled "The Pre-Submission Program and Meetings with Food and Drug Administration Staff." (http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf).

In addition, other FDA guidance documents and resources provide valuable information for preparing 510(k)s, including:

- "Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s" (http://www.fda.gov/RegulatoryInformation/Guidances/ucm084365.htm)
- "The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications – Final Guidance" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080189.pdf)
- "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" (http://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf)
- "eCopy Program for Medical Device Submissions" (http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm313794.pdf)
- "Types of Communication During the Review of Medical Device Submissions" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM341948.pdf)
- "Intent to Exempt Certain Unclassified, Class II, and Class I Reserved Medical Devices from Premarket Notification Requirements" (http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm407292.pdf)
- Other applicable device-specific and cross-cutting guidance documents (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)
- CDRH Device Advice (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm)

V. 510(k) Refuse to Accept Policies and Procedures

FDA staff will conduct an acceptance review of all traditional, special, or abbreviated 510(k)s based on objective criteria using the applicable Acceptance Checklist (see Appendices A - C) to ensure that the 510(k) is administratively complete. In order for the submission to be accepted, all administrative elements identified as RTA items should be present or a rationale should be provided for those elements determined by the submitter to be not applicable. To aid in the administrative review, it is recommended that submitters complete and submit acceptance checklists with their submissions that identify the location of supporting information for each RTA element.

The acceptance review, which occurs prior to the substantive review, should be conducted and completed within 15 calendar days of FDA receiving the 510(k) notification. An acceptance review will only begin for 510(k) submissions for which the appropriate user fee has been paid and a validated eCopy has been received.[2]

The staff will select the applicable checklist based on the 510(k) type (i.e., traditional, special, or abbreviated). The acceptance review will be conducted on original 510(k) submissions and responses to RTA communications, but not supplements or amendments submitted in response to requests for additional information after a submission has been accepted. The staff should assess whether the submission should be accepted by first answering the preliminary questions below, and then verifying that the submission contains all of the information identified as RTA items in the checklist.

The purpose of the 510(k) acceptance review is to assess whether a submission is administratively complete, in that it includes all of the information necessary for FDA to conduct a substantive review. Therefore, the submission should not be accepted and should receive an RTA designation if one or more of the items noted as RTA items in the checklist are not present and no explanation is provided for the omission(s). However, during the RTA review, FDA staff has discretion to determine whether missing checklist items are needed to ensure that the submission is administratively complete to allow the submission to be accepted. FDA staff also has discretion to request missing checklist items interactively from submitters during the RTA review. Interaction during the RTA review is dependent on FDA staff's determination that outstanding issues are appropriate for interactive review and that adequate time is available for the submitter to provide supporting information and for FDA staff to assess responses.

If one or more items noted as RTA items on the Acceptance Checklist are not present, FDA staff conducting the acceptance review should obtain management concurrence and notify the designated 510(k) contact person electronically[3] that the submission has not been accepted.[4]

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[2] For additional information, please see the guidance "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals" available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm.

[3] For additional information about email communications with CBER, please see SOPP 8119: Use of Email for Regulatory Communications, available at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm109645.htm

FDA staff should also provide the submitter with a copy of the completed checklist indicating which item(s) are the basis for the RTA designation.

The 510(k) submitter may respond to the RTA notification by providing the missing information identified in the checklist. The submitter should submit this information to be included in the file under the originally assigned 510(k) number. A new submission and new user fee are not necessary. Nor is it necessary to re-send the entire 510(k) submission, unless FDA notes otherwise (e.g., because the majority of the submission is not in English, or the submission is missing the majority of the items on the checklist). It is sufficient to submit and address only the information requested per the Acceptance Checklist. If a response to the RTA notification is not received within 180 days of the date of RTA notification, FDA will consider the 510(k) to be withdrawn and the submission will be closed in the system.

Upon receipt of the newly submitted information, FDA staff should conduct the acceptance review again following the same procedure within 15 calendar days of receipt of the new information. The subsequent acceptance review will assess whether the new information makes the submission complete according to the checklist criteria for completeness. If the submission is still found to be incomplete, FDA staff should notify the contact person and provide the new checklist indicating the missing item(s).

When a submission is accepted, FDA staff should electronically notify the submission contact person that the 510(k) has been accepted and begin a substantive review of the submission to determine substantial equivalence. Should FDA fail or choose not to complete the acceptance review within the acceptance review period (i.e., within 15 calendar days of receipt), the submitter should be electronically notified that the acceptance review was not completed and the submission is under substantive review. FDA may request any information that may have resulted in an RTA designation during the substantive review.[5] Once a submission has been accepted, FDA may ask for any information during the substantive review that may have been unintentionally overlooked during the acceptance review.

FDA Review Clock

As explained in the commitment letter for MDUFA III referenced in Title II of FDASIA, Public Law 112-114, "FDA days begin on the date of receipt of the submission or of the amendment to the submission that enables the submission to be accepted (510(k)) or filed (PMA)."[6] Thus, the FDA review clock does not start when a submission is placed on eCopy or User Fee hold or designated RTA.

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[4] As outlined in the commitment letter for MDUFA III [FDA, "MDUFA Performance Goals and Procedures" (April 18, 2012), available at http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf) (attachment to letter dated July 16, 2012 from Secretary of Health and Human Services Kathleen Sebelius to The Honorable Fred Upton, Chairman, U.S. House of Representatives Committee on Energy & Commerce)], the review clock will not start until the 510(k) submission is accepted for review.

[5] In the case of a government closure during the 15-day review period, the review period may be extended by a comparable number of business days that the FDA buildings are closed. If the submitter receives an automated notice that the acceptance review was not completed because the screening period has exceeded 15 days, FDA may send a correction notice to the submitter.

[6] FDA, "MDUFA Performance Goals and Procedures" (April 18, 2012), available at http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf)

510(k) submissions and additional information submitted in response to a RTA designation are received by the respective Center's Document Control Center (DCC). The FDA review clock start date is the DCC receipt date of the most recent submission or additional information that resulted in an acceptance designation for the 510(k), provided the submission user fee has been paid and a validated eCopy has been provided. For example, if the submission is accepted for substantive review on the first acceptance review, the FDA review clock start date is the DCC receipt date of the submission. However, if the submission is designated RTA, the FDA review clock start date is not yet known. In such cases, the clock start date will be the DCC receipt date of the submission including the additional information that results in an acceptance designation (even if FDA later requests information that should have been requested during acceptance review.) In the event the acceptance review was not completed within 15 calendar days, the submission will be considered to be under substantive review, and the FDA review clock start date will be the DCC receipt date of the most recently received information for the submission. Once the submission is under substantive review the calendar days used to conduct the acceptance review (i.e., up to 15 days) are included within the 60 calendar days to reach the Substantive Interaction goal as described in the aforementioned commitment letter for MDUFA III.

Notification of Acceptance Review Result

The submitter should receive an electronic notification of the acceptance review result within 15 calendar days of DCC receipt (i.e., that the submission has been accepted for substantive review, that the submission is not accepted for review (RTA), or that the submission is now under substantive review because the acceptance review was not completed). This notification will also serve to identify the FDA lead reviewer[7] assigned to the submission. The notification of either the acceptance or RTA designation will be made only with supervisory concurrence of the reviewer's acceptance review determination. The notification of acceptance or RTA designation may occur on any day prior to the 15th calendar day of DCC receipt. However, in the event the acceptance review was not conducted, a notification that an RTA review was not conducted will be sent on the 16th day. The notification will be sent only to the designated contact person identified in the submission. In the case of RTA designation, the notification should be accompanied by the completed checklist indicating the missing elements that resulted in the RTA designation. The completed checklists are considered part of the submission's administrative file and will not be posted publicly. Therefore, it is imperative that the submission identify complete contact information, including the email address to which the notification should be sent.[8]

(attachment to letter dated July 16, 2012 from Secretary of Health and Human Services Kathleen Sebelius to The Honorable Fred Upton, Chairman, U.S. House of Representatives Committee on Energy & Commerce)

[7] In the case of 510(k)s submitted to CBER, whenever the term lead reviewer is used in this guidance, the equivalent CBER contact person is the regulatory project manager (RPM).

[8] CBER will accommodate the use of faxes; submitters may also wish to provide a fax number.

VI. Refuse to Accept Principles

In order to use this guidance appropriately, FDA staff should review the following basic principles regarding FDA's review policies and procedures.

Acceptance should not be based on a substantive review of the information provided in the 510(k) notification.

It is important to make the distinction between the acceptance review and the substantive review. The acceptance review is conducted to assess whether the submission contains all of the appropriate elements, as identified in the applicable checklist, in order to begin a substantive review. In assessing whether a 510(k) notification should be accepted, submitted information is not evaluated for adequacy to support a finding of substantial equivalence. The checklist is a tool to ensure that the submission contains the necessary information in order to conduct a
substantive review (i.e., FDA should not refuse to accept a submission if information is present but inadequate to support a finding of substantial equivalence). The evaluation of the quality of the content and the substantial equivalence decision making process occur within the substantive review once the file has been accepted.

FDA staff should determine whether the submitter provided a justification for any alternative approach

The submitter may provide a rationale for why any criteria in the checklist are not applicable to the device. Likewise, the submitter may provide a rationale for any deviation from a device- specific or cross-cutting guidance document or FDA-recognized standard. It is FDA's expectation that each item in the checklist will be addressed either by including the requested information or providing a rationale for why is it not applicable or why there is a deviation. FDA will not consider a given criterion in the checklist to be "Present" if the submission fails to include either the information requested or a rationale for omission or deviation. If a justification to omit certain information or for taking an alternative approach is provided, FDA will consider the adequacy of that justification or alternative approach during substantive review of the submission. See Acceptance Review section below for examples and further explanation.

Device-specific and cross-cutting guidance documents, applicable recognized standards, and applicable regulations will be considered when making an RTA determination.

Before submitting a 510(k), the submitter should consider the currently available guidance documents and standards, as well as applicable regulations for the proposed device in the preparation of the submission. FDA staff and industry are encouraged to refer to the product classification database
(http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm) to assist in identifying any applicable recognized consensus standards and product specific guidance document(s).

Specifically, the checklist includes questions regarding whether the submission has addressed recommendations regarding the device description, labeling, and performance testing as outlined in a device-specific guidance, special controls or another specific regulation, or a special controls guideline. Note that "addressed" means that the submission includes information pertinent to those recommendations or requirements; assessment of the adequacy of that information in meeting those recommendations or requirements should be assessed during review.

If there is a device-specific guidance, other than a special controls guidance document, the submission includes information to establish that the submitter has addressed the recommendations or otherwise provided an alternative approach intended to address the applicable statutory and/or regulatory criteria.

If there are special controls in a device-specific guideline, guidance document, or regulation applicable to the device, the submission includes information addressing the particular mitigation measures set forth in the special controls guideline, guidance document, or regulation, or uses alternative mitigation measures and provides a rationale to demonstrate that those alternative measures identified by the submitter will provide at least an equivalent assurance of safety and effectiveness.

VII. The Checklist – Preliminary Questions

Within 15 calendar days of receipt of the 510(k), FDA staff should answer the preliminary questions below, which are included on the first page of the Acceptance Checklists. The preliminary questions are intended to be answered by the lead reviewer as an initial screening of the submission. FDA does not intend for the applicant to have addressed these items in their submission. Depending upon the answers to these preliminary questions, the remainder of the acceptance review may or may not be necessary.

If the responses to the preliminary questions and subsequent consultation with the Center personnel identified below indicate that the 510(k) acceptance review should not continue[9] the 510(k) reviewer or RPM should promptly:

- inform the 510(k) review team (including consulting reviewers), and
- notify the submitter using proper administrative procedures.

The preliminary questions are:

[9] FDA will not process a 510(k) unless it meets the following requirements: i) the submission must be sent with the user fee required by section 738 of the FD&C Act, and ii) the firm must submit the correct number of copies per 21 CFR 807.90(c). FDA has issued guidance to implement section 1136 of FDASIA, which added Section 745A(b) of the FDA&C Act ("eCopy Program for Medical Device Submissions," available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794. pdf). . Since any 510(k) not meeting these two requirements will not be processed by the CDRH Document Mail Center or the CBER RPM, they are not included in the checklist.

1. **Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)?**

   If the product does not appear to meet the definition of a device under section 201(h) of the FD&C Act, or does not appear to be a combination product with a device constituent part, then the 510(k) lead reviewer should consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action, and inform division management. If FDA staff determines that the product is not a device and is not a combination product with a device constituent part, the 510(k) review team should stop the review and notify the submitter..

2. **Is the submission with the appropriate Center?**

   If the submission is for a single-entity device and appears to be subject to review in a Center different from the one to which it was submitted, or if it is for a combination product with a device constituent part and it appears that a Center different from the one to which it was submitted has the lead, the 510(k) lead reviewer should consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform division management. If the 510(k) is submitted to CDRH and CDRH staff determines that the submission is not subject to CDRH review, or the 510(k) is submitted to CBER and CBER staff determines that the submission is not subject to CBER review, the 510(k) review team should stop the review and notify the submitter.

3. **If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following:**
   - **Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?**
   - **Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?**

   An RFD determination is specific to the device or combination product and indications for use for the device or combination product described in the RFD submission. If the device or combination product has been modified or the indications for use have been modified since the RFD, the RFD determination may no longer be applicable and jurisdiction may need to be reevaluated by the Office of Combination Products (OCP). The 510(k) lead reviewer should consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform division management.

4. **Is this device type eligible for a 510(k) submission?**

   FDA staff should determine whether the 510(k) submission is for a device type for which 510(k) is known to be an inappropriate regulatory approach, such as when the

device type is Class III type and a PMA is required, or the device type is Class I or II and 510(k)-exempt. If a 510(k) is not appropriate, FDA staff should make this determination during the acceptance review and notify the submitter of the determination. This preliminary question is not intended to identify submissions for which a substantive review is required in order to determine if 510(k) is an inappropriate approach (e.g., device has a new intended use or device has different technological characteristics that raise different questions of safety and effectiveness).

5. **Is there a pending PMA for the same device with the same indications for use?**

   If the submitter has a PMA for the same device with the same indications for use pending, the review team should stop the review. The 510(k) review team should consult division management and other Center resources to determine which premarket review pathway applies to the device and the appropriate processes for addressing the situation. FDA staff should also consult division management and other Center resources if a 510(k) and PMA have been submitted for the same device type by different applicants.

6. **If clinical studies have been submitted, is the submitter the subject of the Application Integrity Policy (AIP)?**[10]

   The lead reviewer should refer to the AIP list (http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm). If the applicant is on the list, the reviewer should consult the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/ Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action.

VIII. The Checklists – Acceptance Review

Organizational Elements
Although missing one or more of the items in the table of Organizational Elements in the Acceptance Checklists, such as a Table of Contents or page numbers, generally will not lead to an RTA decision, we strongly encourage submitters to incorporate these elements in their submissions to streamline FDA review and decision-making. If, however, the submission is so disorganized that FDA cannot locate the information needed to assess substantial equivalence, or if the submission is so poorly written (e.g., in broken English) that the information submitted to support substantial equivalence cannot be understood, the submission should receive an RTA decision.

[10] When data in a pending submission have been called into question by certain wrongful acts (fraud, untrue statements of material facts, bribery, or illegal gratuities), FDA intends to defer substantive scientific review of such data until completion of a validity assessment and questions regarding reliability of the data are resolved. (*See* FDA Guide 7150.09 Compliance Policy Guide, Chapter 50 – General Policy – Subject: Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities, 56 FR 46191.)

Elements of a Complete Submission (RTA Items)
The objective criteria in these checklists outline those elements that are explicitly required by regulation or that are essential to FDA's substantive review of the submission and determination of substantial equivalence under section 513(i) of the FD&C Act. For example, proposed labels, labeling, and instructions are required by 21 CFR 807.87(e)), while a description of the materials, design, and other features of the device is essential to determining whether its technological characteristics are the same as those of the predicate and whether any differences raise different questions of safety and effectiveness under section 513(i) of the FD&C Act.

We have also identified several categories and subcategories of data and information that, when applicable, are critical to supporting a statement indicating the device is similar to and/or different from other products of comparable type under 21 CFR 807.87(f) and the substantial equivalence determination. For example, if the new device has direct or indirect patient-contacting components, a biocompatibility assessment will be essential to evaluating whether the new device is as safe as the predicate with respect to the risk of toxicity it poses to the patient. While testing and data would usually be necessary for such an assessment, this is not always the case (for example if the device under review and the predicate are identical in all relevant respects), and acceptance should be based only on the presence of an item or an explanation why the item is not applicable, not the adequacy of such explanation. If the device has no direct or indirect patient-contacting components, no biocompatibility assessment would be necessary and the biocompatibility items on the checklist would be not applicable.

Because the applicability of these categories is also critical to the substantial equivalence determination, in order to be accepted, all submissions should include a statement indicating whether these categories apply, as outlined in the Acceptance Checklist (e.g., materials, presence of software, whether the device is intended to be used sterile). When performance data are provided, the submission of full test reports describing how the testing was conducted is crucial to FDA's assessment of whether the data support a finding of substantial equivalence.

Where a device-specific guidance document exists for the subject device, the submitter should follow the recommendations included in that document, or the submitter should provide a rationale for addressing the scientific issues discussed in the guidance document using an alternative approach intended to address the applicable statutory and/or regulatory criteria. In the absence of the recommended information and without a rationale for an alternative approach, the submission should be considered incomplete and not accepted. If special controls have been identified or a special controls guideline exists for the device, those controls should be addressed in order for the submission to be accepted, or alternative mitigation measures providing a rationale to demonstrate that those alternative measures will provide at least an equivalent assurance of safety and effectiveness should be identified.

Applying the Checklist of RTA Items
Using the Acceptance Checklist appropriate to the submission type (traditional, abbreviated, or special), within 15 calendar days of receipt of the 510(k), FDA staff should answer each

question for the elements identified as RTA items. For those items that have an option of "yes," "no," or "not applicable (N/A)" as an answer, the item should receive an answer of "yes" or "N/A" for the 510(k) submission to be accepted for substantive review.

For the first question in each section related to the need for certain performance data (such as biocompatibility, sterilization, software, etc.), FDA staff should indicate whether the submission has addressed one of the options for the 510(k) submission to be accepted for substantive review. For example, the submission should state explicitly that either there are or are not direct or indirect (e.g., through fluid infusion) patient-contacting components in order for the submission to be considered complete and accepted for substantive review.

Elements marked "Not applicable"
In developing the checklists, the Agency has considered the general categories and respective subcategories of information that are necessary to conduct a substantive review for the wide range of medical devices that are appropriate for review under 510(k) premarket notification. All such criteria may not be pertinent to a particular device. FDA staff should select "N/A" for those elements that do not apply to the subject device. For example, the requirements for financial certification and disclosure statements (21 CFR 807.87(i)) only apply to submissions with clinical data. If the submission contains no clinical data, FDA staff should select "N/A."

Adequacy of information
In order to make the checklist criteria objective, for each RTA item, FDA should consider only the presence or omission of the element or a rationale for the omission of the element or use of an alternative approach during acceptance review. It is likely that FDA staff will encounter scenarios where information is provided, but is incomplete or inadequate. In such instances, FDA staff should answer the question for the respective item as "Yes," but may communicate the inadequacy or request additional information in the course of the substantive review. For example, the submitter may have provided full test reports for all performance testing; however, during the acceptance review, the reviewer may note that the *results* of a particular test may not be sufficient to support a finding of substantial equivalence and additional justification would be needed. The performance testing criterion would be marked "Yes" in the checklist, and the full assessment of the results and communication to the submitter that additional justification is needed should occur during the substantive review.

Elements marked "No"
For any acceptance criterion designated as "No," FDA intends to provide an explanation to describe the missing element(s), if needed. This explanation is particularly important for a criterion in which it may not be immediately apparent to the submitter what necessary information, specifically, is not present. For example, the Device Description section includes an element that states "submission addresses device description recommendations outlined in the device- specific guidance document" and a notation of "No" alone may not be sufficient to inform the submitter of what specific piece(s) of information is missing. FDA staff should include a list or statement of the additional information that is necessary to meet the acceptance criteria. This list or statement can be communicated in the "comment" section on the checklist beside each specific criterion.

Prior Submissions Relevant to the Submission Under Review
For certain submissions, the submitter may have made prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., a Pre-Submission, IDE, prior NSE determination, prior 510(k) that was deleted or withdrawn). When such prior feedback relevant to determining substantial equivalence of the subject device exists, the new submission should include information to address this prior feedback and the checklists include criteria related to this issue. To address the criterion regarding whether a prior submission (or no prior submission) exists, FDA recommends that submitters provide this information in Section F (prior related submissions section) of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf). Submitters should list prior submission numbers in Section F of this form or state that there were no prior submissions to address this criterion. Please be advised that leaving this section of the form blank will not be considered a statement that there were no prior submissions. This information may also be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the numbers(s) of the prior submission(s)). Where one or more prior submissions do exist, FDA suggests designating a separate section of the submission that identifies the prior submission(s) by number, includes a copy of the FDA feedback (e.g., letter, meeting minutes), and states how or where in the submission this prior feedback was addressed. Note that the adequacy of how the feedback was addressed should be assessed during the substantive review.

Conversion of Special 510(k) to Traditional 510(k)
FDA has developed separate checklists to address the differences in content for special and traditional 510(k) submissions. FDA staff will utilize the appropriate checklist based on the file type as designated by the submitter. In the event that the submitter has submitted a special 510(k), but FDA determines that the file should be converted to a traditional 510(k)[11] FDA will notify the contact person designated in the 510(k) submission of the conversion and the rationale for the conversion. If the file is converted from a special to a traditional within the 15 calendar day acceptance review period, the Traditional 510(k) Acceptance Checklist will be used to conduct the acceptance review and the review clock start date will be assigned as outlined in the 510(k) Refuse to Accept Policies and Procedures section above. Given the differences in content requirements for special and traditional 510(k)s, it is likely that the converted submission will result in an RTA designation using the Traditional Acceptance Checklist. FDA staff should provide the completed Acceptance Checklist for traditional submissions indicating which elements are missing. The submitter may respond by providing the identified information and the subsequent acceptance review will proceed with the traditional checklist. If the file is converted from a special to a traditional after the 15 calendar day acceptance review period, any missing information that would have resulted in RTA designation should be obtained during the substantive review.

[11] Please see "Special 510(k) Criteria," items 1-4 of the Acceptance Checklist for Special 510(k)s for potential reasons for conversion.

Appendix A

Contains Nonbinding Recommendations

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k)#: K **Date Received by DCC:**

Lead Reviewer:

Branch: **Division:** **Center/Office:**

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review.)

	Yes	No	N/A
1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	☐	☐	
Comments:			
2. Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If submission should not be reviewed by your Center mark "No."	☐	☐	
Comments:			

3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."	☐	☐	☐
Comments:			
4. Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	☐	☐	
Comments:			
5. Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.	☐	☐	
Comments:			
6. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm. If no clinical studies have been submitted, mark "N/A."	☐	☐	☐
Comments:			

- **If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.**
- **If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.**

- **If the answer to 4 is "No", the lead reviewer should consult division management and other Center resources to determine the appropriate action.**
- **If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.**
- **If the answer to 6 is "Yes," then contact CDRH/OC/DBM or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DBM or BMB Staff, and indicate their recommendation/action.**

Organizational Elements Failure to include these items should not result in an RTA designation.				
***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**		**Yes**	**No**	***Page #**
1.	Submission contains a Table of Contents.	☐	☐	
2.	Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.).	☐	☐	
3.	All pages of the submission are numbered. *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☐	☐	
4.	Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special) *If type of 510(k) is not designated, review as a Traditional 510(k).*	☐	☐	
Comments:				

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed
• Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during the RTA review. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
A.	**Administrative**						
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.).		☐	☐		
		Comments:					
	2.	Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
		a.	Device trade/proprietary name	☐	☐		
		b.	Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	☐	☐		
		Comments:					
	3.	Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") *See recommended format (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).*		☐	☐		
		Comments:					
	4.	Submission contains a 510(k) Summary or 510(k) Statement. *Refer to 21 CFR 807.92 and 21 CFR 807.93 for contents of 510(k) Summary and Statement, respectively. Adequacy of the content will be assessed during substantive review.*		☐	☐		
		Comments:					
	5.	Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k). *See recommended format (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).*		☐	☐		
		Comments:					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	6.	Submission is a Class III 510(k) Device. *Select "N/A" only if submission is not a Class III 510(k).*		☐		☐	
		a.	Contains Class III Summary and Certification *See recommended content (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142662.htm). Select "N/A" only if submission is not a Class III 510(k).*	☐	☐	☐	
		Comments:					
	7.	Submission contains clinical data. *Select "N/A" if the submission does not contain clinical data. If "N/A"is selected, parts a and b below are omitted from the checklist.*		☐		☐	
		a.	Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each covered clinical study included in the submission. *Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the Guidance for Industry-Financial Disclosures by Clinical Investigators.*	☐	☐	☐	
		b.	Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. *Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j)*	☐	☐	☐	
		Comments:					
	8.	The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device. *Prior submissions (or no prior submissions) for this device should be included in Section F (prior related submissions) of the CDRH Premarket Review Submission Cover Sheet form (Form 3514).*		☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		This information may also be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions).					
		a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed. *To address this criterion, it is recommended that the submission include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that adequacy of how the feedback was addressed will be assessed during the substantive review.* *Select "N/A" if the submitter states there were no prior submissions.*	☐	☐	☐	
		Comments:					
B.	**Device Description**						
	9.	The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device. *If "N/A"is selected, parts a and b below are omitted from the checklist.*		☐		☐	
		a.	The submission addresses device description recommendations outlined in the device-specific guidance. **<u>OR</u>** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		b.	The submission includes device description information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		Comments:					
	10.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).		☐	☐		
		Comments:					
	11.	The submission includes descriptive information for the device, including the following:					
		a.	A description of the principle of operation or mechanism of action for achieving the intended effect.	☐	☐		
		b.	A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☐	☐		
		c.	A list and description of each device for which clearance is requested. *Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, various sizes, etc.*	☐	☐	☐	
		d.	Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR**	☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
			Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device). *In lieu of engineering drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.*				
		Comments:					
	12.	Device is intended to be marketed with multiple components, accessories, and/or as part of a system. *Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system. If "N/A"is selected, parts a-c below are omitted from the checklist.*		☐		☐	
		a.	Submission includes a list of all components and accessories to be marketed with the subject device.	☐	☐		
		b.	Submission includes a description (as detailed in item 11a., 11b., and 11d. above) of each component or accessory. *Select "N/A" if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.*	☐	☐	☐	
		c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance **AND** A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.	☐	☐		
		Comments:					
C.	**Substantial Equivalence Discussion**						
	13.	Submitter has identified a predicate device(s), including the following information:					
		a.	Predicate device identifier provided (e.g., 510(k) number, de	☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
			novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm).*				
		b.	The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	☐	☐		
		Comments:					
	14.	Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.*					
		a.	Indications for use *If there are no differences between the subject device and the predicate(s) with respect to indications and intended use, this should be explicitly stated.*	☐	☐		
		b.	Technology, including features, materials, and principles of operation *Examples of technological characteristics include, but are not limited to design, features, materials, energy source, and principle of operation.* *FDA recommends a tabular format for comparing technological characteristics. Any characteristic that is the*	☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
			same as the predicate(s) should be explicitly stated. Differences in technological characteristics should be identified and a rationale provided why they do not raise different questions of safety and effectiveness.				
		Comments:					
D.	**Proposed Labeling (see also 21 CFR parts 801 and 809 as applicable)**						
	15.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).		☐	☐		
		a.	Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided)	☐	☐		
		b.	Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☐	☐		
		Comments:					
	16.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)		☐	☐		
		Comments:					
	17.	Labeling includes the prescription statement (see 21 CFR 801.109(b)(1)) or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements"). *Select "N/A" if not indicated for prescription use.*		☐	☐	☐	
		Comments:					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	18.	The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding labeling that is applicable to the subject device. *If "N/A"is selected, parts a and b below are omitted from the checklist.*		☐		☐	
		a.	The submission addresses labeling recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes labeling information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		Comments:					
	19.	If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. Select "N/A" if not an in vitro diagnostic device.		☐	☐	☐	

			Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**	**Yes**	**No**	**N/A**	***Page #**
		Comment:					
E.	**Sterilization** *If an in vitro diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*					☐	
	Submission states that the device, and/or accessories, and/or components are: (*one of the below must be checked*) ☐ Provided sterile, intended to be single-use ☐ Requires processing during its use-life ☐ Non-sterile when used (and no processing required) ☐ Information regarding the sterility status of the device is not provided (if this box is checked, please also check one of the two boxes below) ☐ Sterility status not needed for this device (e.g., software-only device) ☐ Sterility status needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "non-sterile when used" or "not provided and not needed" is selected, the sterility-related criteria below are omitted from the checklist.* *If information on sterility status is not provided, and it is needed or the need for this information is unclear, select "No."* *The "Requires processing during its use-life" option refers to devices falling into one of the four categories below:* • *Supplied sterile and requires reprocessing prior to subsequent patient use* • *Supplied non-sterile and requires user to process the device for initial use, as well as to reprocess the device after each use* • *Reusable medical device (single-user) reprocessed between each use* • *Single-use medical devices initially supplied as non-sterile to the user, and requiring the user to process the device prior to its use* *Please refer to the guidance document titled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" for additional information.*			☐		
	Comments:						
	20.	Assessment of the need for cleaning and subsequent disinfection					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		or sterilization information.					
		a.	Identification of device, and/or accessories, and/or components that are provided sterile. *Select "N/A" if no part of the device, accessories, or components is provided sterile.*	☐	☐	☐	
		b.	Identification of device, and/or accessories, and/or components that are end user sterilized or disinfected. *Select "N/A" if no part of the device, accessories, or components is end user sterilized or disinfected.*	☐	☐	☐	
		c.	Identification of device, and/or accessories, and/or components that are reusable. *Select "N/A" if no part of the device, accessories, or components is reusable.*	☐	☐	☐	
		Comments:					
	21.	If the device, and/or accessory, and/or a component is provided sterile: *Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-f below.*				☐	
		a.	Sterilization method is stated for each component (including dose for radiation sterilization)	☐	☐		
		b.	A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date). *Note: the sterilization validation report is not required.*	☐	☐		
		c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits. *Select "N/A" if not sterilized using chemical sterilants.*	☐	☐	☐	
		d.	Sterility Assurance Level (SAL) stated	☐	☐		
		e.	Submission includes description of packaging	☐	☐		
		f.	For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus	☐	☐	☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**					**Yes**	**No**	**N/A**	***Page #**
				amebocyte lysate [LAL]). *Select "N/A" if not labeled "non-pyrogenic."*				
		Comments:						
	22.	If the device, and/or accessory, and/or a component is reusable or end user sterilized or disinfected: *Select "N/A" if no part of the device, accessories, or components are reusable or end user sterilized or disinfected, otherwise complete a-d below.*					☐	
		a.	Cleaning method is provided in labeling for each device, and/or accessory, and/or component. *Select "N/A" if not reusable and does not need cleaning prior to disinfection or sterilization*		☐	☐	☐	
		b.	Disinfection method is provided in labeling for each device, and/or accessory, and/or component. *Select "N/A" if not disinfected (i.e., undergoes terminal sterilization) prior to use*		☐	☐	☐	
		c.	Sterilization method is provided in labeling for each device and/or accessory, and/or component. *Select "N/A" if not sterilized (i.e., undergoes disinfection) prior to use*		☐	☐	☐	
		d.	Device types in this submission are listed in Appendix E of the FDA's guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling." *Device types identified in Appendix E of the reprocessing guidance represent devices posing a greater likelihood of microbial transmission and represent a high risk of infection. Select "N/A" if the device type in the submission is not included in Appendix E of the reprocessing guidance.*		☐		☐	
			i.	If device types in this submission are included in Appendix E of the reprocessing guidance, the submission includes protocols and test reports for validating the reprocessing instructions. *Select "N/A" if the device type in the submission is not included in Appendix E of the reprocessing guidance.*	☐	☐	☐	
		Comments:						

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	23.	The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device *If "N/A"is selected, parts a and b below are omitted from the checklist.*		☐		☐	
		a.	The submission addresses sterility and/or reprocessing recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes sterility and/or reprocessing information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		Comments:					
F.	**Shelf-Life**						

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
	24.	Proposed shelf life/ expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	☐	☐		
		Comments:				
	25.	For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf-life. *Select "N/A" if the device is not provided sterile.*	☐	☐	☐	
		Comments:				
	26.	Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	☐	☐		
		Comments:				
G.	**Biocompatibility** *If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*				☐	
	Submission states that there: (*one of the below must be checked*) ☐ Are direct or indirect patient-contacting components ☐ Are no direct or indirect patient-contacting components ☐ Information regarding patient contact status of the device is not provided (if this box checked, please also check one of the two boxes below) ☐ Patient contact information not needed for this device (e.g., software-only device) ☐ Patient contact information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.			☐		

	Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**		**Yes**	**No**	**N/A**	***Page #**
	If "are no" or "not provided and not needed" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information on the patient-contact status is not provided, and contact information is needed or its contact status is unclear, select "No." *An example of a direct patient-contacting device would be an implant that has direct contact with patient tissues during use. An example of an indirect patient-contacting device would be fluid entering the patient's body following passing through device/device components not in direct contact with the patient.*					
	Comments:					
	27.	Submission includes a list identifying each patient-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	☐	☐		
		Comments:				
	28.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration) for each patient-contacting device component (e.g., implant, delivery catheter).	☐	☐		
		Comments:				
	29.	Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	☐	☐		
		Comments:				
H.	**Software**					
	Submission states that the device: (*one of the below must be checked*) ☐ Does contain software/firmware			☐		

			Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**	**Yes**	**No**	**N/A**	***Page #**
	☐ Does not contain software/firmware ☐ Information on whether device contains software/firmware is not provided (if this box checked, please also check one of the two boxes below) ☐ Software/firmware information not needed for this device (e.g., surgical suture, condom) ☐ Software/firmware information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not contain" or "not provided and not needed" is selected, the software-related criteria below are omitted from the checklist. If information on software is not provided, and this information is needed or the need is unclear, select "No."*						
	Comments:						
	30.		Submission includes a statement of software level of concern and rationale for the software level of concern	☐	☐		
			Comments:				
	31.		All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale). *Note: This element is also applicable to non-internally generated or off-the-shelf (OTS) software used in the device.*	☐	☐		
			Comments:				
I.	**Electrical Safety and EMC**						
	Electrical Safety: Submission states that the device: (*one of the below must be checked*) ☐ Does require electrical safety evaluation ☐ Does not require electrical safety evaluation				☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
	☐ Information on whether device requires electrical safety evaluation not provided (if this box checked, please also check one of the two boxes below) ☐ Electrical safety information not needed for this device (e.g., surgical suture, condom) ☐ Electrical safety information needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not require" or "not provided and not needed" is selected, the electrical safety criteria below are omitted from the checklist. If information on electrical safety is not provided, and it is needed or the need for this information is unclear, select "No."*					
	Comments:					
	32.	Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, a device-specific standard). **<u>OR</u>** Submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☐	☐		
		Comments:				
	EMC: Submission states that the device: (*one of the below must be checked*) ☐ Does require EMC evaluation ☐ Does not require EMC evaluation ☐ Information on whether device requires EMC evaluation not provided (if this box checked, please also check one of the two boxes below) ☐ EMC information not needed for this device (e.g., surgical suture, condom) ☐ EMC information needed or need unclear			☐		

				Yes	No	N/A	*Page #
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not require" or "not provided and not needed" is selected, the EMC criteria below are omitted from the checklist. If information on EMC is not provided, and it is needed or the need for this information is unclear, select "No."*						
	Comments:						
	33.	Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, a device-specific standard). **OR** Submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).		☐	☐		
		Comments:					
J.	**Performance Data General** *If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.*					☐	
	Comments:						
	34.	Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions. *Full test reports provided for all completed tests/evaluations (e.g., bench evaluations, comparative performance tests, etc.). Select "N/A" if the submission does not include performance data.*		☐	☐	☐	
		a.	Submission includes an explanation of how the data generated from each test report supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).	☐	☐	☐	

				Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**	**Yes**	**No**	**N/A**	***Page #**
				Select "N/A" if the submission does not include performance data.				
		Comments:						
	35.	The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding performance data that is applicable to the subject device *If "N/A"is selected, parts a and b below are omitted from the checklist.*			☐		☐	
		a.	The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*		☐	☐	☐	
		b.	The submission includes performance data that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*		☐	☐	☐	
		Comments:						

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	36.	If literature is referenced in the submission, submission includes: *Select "N/A" if the submission does not reference literature. If "N/A"is selected, parts a and b below are omitted from the checklist.* *Note that the applicability of the referenced article to support a substantial equivalence finding should be assessed during the substantive review; only the presence of a discussion is required to support acceptance.*				☐	
		a.	Legible reprints or a summary of each article.	☐	☐		
		b.	Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	☐	☐		
		Comments:					
	37.	For each completed animal study, the submission provides the following: *Select "N/A" if no animal study was conducted. If "N/A"is selected, parts a-c below are omitted from the checklist. Note that this section does not address biocompatibility evaluations, which are assessed in Section G of the checklist.*				☐	
		a.	Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120	☐	☐		
		b.	Submission includes final study report which includes all elements outlined in 21 CFR 58.185	☐	☐		
		c.	Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	☐	☐		
		Comments:					
K.	**Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))**						
	Submission indicates that device: (*one of the below must be checked*) ☐ Is an in vitro diagnostic device						

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	☐ Is not an in vitro diagnostic device *If "is not" is selected, the performance data-related criteria below are omitted from the checklist.*						
	38.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:					
		a.	Precision/reproducibility	☐	☐	☐	
		b.	Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff.	☐	☐	☐	
		c.	Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).	☐	☐	☐	
		d.	Analytical specificity	☐	☐	☐	
		Comments:					
	39.	The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulations regarding performance data that is applicable to the subject device. *If "N/A"is selected, parts a and b below are omitted from the checklist.*		☐	☐	☐	
		a.	The submission addresses performance data recommendations outlined in the device-specific guidance. **<u>OR</u>** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes performance data that addresses	☐	☐	☐	

			Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**	**Yes**	**No**	**N/A**	***Page #**
			relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*				
		Comments:					

Decision: Accept_____ Refuse to Accept_____

If Accept, notify the applicant

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

*Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

Appendix B

Contains Nonbinding Recommendations

Acceptance Checklist for Abbreviated 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k)#: K **Date Received by DCC:**

Lead Reviewer:

Branch: **Division:** **Center/Office:**

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review.)

	Yes	No	N/A
1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	☐	☐	
Comments:			
2. Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If submission should not be reviewed by your Center mark "No."	☐	☐	
Comments:			

3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."	☐	☐	☐
Comments:			
4. Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	☐	☐	
Comments:			
5. Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.	☐	☐	
Comments:			
6. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm. If no clinical studies have been submitted, mark "N/A."	☐	☐	☐
Comments:			

- **If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.**
- **If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.**

- **If the answer to 4 is "No", the lead reviewer should consult division management and other Center resources to determine the appropriate action.**
- **If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.**
- **If the answer to 6 is "Yes," then contact CDRH/OC/DBM or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DBM or BMB Staff, and indicate their recommendation/action.**

Abbreviated 510(k) Criteria

(See "The new 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications – Final Guidance" and "Format for Traditional and Abbreviated 510(k)s")

In order to qualify for review as an Abbreviated 510(k), one of the following criteria (1 or 2 or 3) should be met. Submission should be converted and reviewed as a Traditional 510(k) if one of these criteria is not met. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.

			Yes	No	N/A
1.		**Submission relies on a device-specific guidance document, other than a special controls guidance document, and a summary report is provided that:** *Select "N/A" if submission does not rely on any device-specific guidance document(s). If "Yes," address parts a and b below.*	☐		☐
	a.	Includes a description of adherence to the relevant guidance document to support substantial equivalence.	☐	☐	
	b.	Includes a description of how the guidance document was used to satisfy the requirements of 21 CFR 807.87 (e.g., data to support substantial equivalence) and lists any deviations. *Select "No" if the sponsor does not address whether there were deviations.*	☐	☐	
Comments:					
2.		**Submission relies on a special control(s), either in a device-specific regulation or special controls document, as defined in Section 513(a)(1)(B) of the FD&C Act, to demonstrate substantial equivalence and a summary report is provided that:** *Select "N/A" if submission does not rely on any special controls. If "Yes," address parts a-d below.*	☐		☐
	a.	Includes a description of adherence to the special control(s) to support substantial equivalence	☐	☐	
	b.	Includes a description of how the special control(s) was used to satisfy the requirements of 21 CFR 807.87 (e.g., data to support substantial equivalence) and lists any deviations	☐	☐	

		Select "No" if the sponsor does not address whether there were deviations.			☐	☐
Comments:						
3. Submission relies on FDA-recognized consensus standard(s) (See section 514(c)). *Select "N/A" if submission does not rely on any FDA-recognized standard(s). If "Yes," address part a below.*					☐	☐
		For each cited standard:				
	a.	Submission includes: - The device specific conformity statement as specified in device-specific guidance document (e.g., latex condoms), or - a declaration for conformity to the device specific standard. **OR** The items below for use of FDA-recognized consensus standards.			☐	☐ ☐
		i.	An identification of the applicable FDA-recognized consensus standards (full citation including version number)		☐	☐ ☐
		ii.	An identification, for each consensus standard, of any adaptations of the standard for evaluation of the device under review (e.g., an identification of an alternative series of tests that were performed)		☐	☐ ☐
		iii.	An identification, for each consensus standard, of any items (e.g., normative requirements of the standard) applicable to your device		☐	☐ ☐
		iv.	A specification of any deviations from each applicable standard (e.g., deviations from international standards which are necessary to meet U.S. infrastructure conventions such as the National Electrical Code (ANSI/NFPA 70))		☐	☐ ☐
		v.	A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification for the applicability of the test results in these areas of differences.		☐	☐ ☐
Comments:						

Does the submission meet one of the criteria above?

☐ Yes, submission meets criteria for an Abbreviated 510(k). Continue with the remainder of this checklist below.

☐ No, submission does not meet criteria for an Abbreviated 510(k). Discontinue this RTA checklist, convert to a Traditional and apply the Traditional checklist.

Organizational Elements Failure to include these items should not result in an RTA designation.				
***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**		**Yes**	**No**	***Page #**
1.	Submission contains a Table of Contents.	☐	☐	
2.	Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.).	☐	☐	
3.	All pages of the submission are numbered. *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☐	☐	
4.	Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special) *If type of 510(k) is not designated, review as a Traditional 510(k).*	☐	☐	
Comments:				

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed
• Any "No" answer will result in a "Refuse to Accept" decision.; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during the RTA review. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**		**Yes**	**No**	**N/A**	***Page #**
A.	**Administrative**				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.).		☐	☐		
		Comments:					
	2.	Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
		a.	Device trade/proprietary name	☐	☐		
		b.	Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	☐	☐		
		Comments:					
	3.	Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") *See recommended format (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).*		☐	☐		
		Comments:					
	4.	Submission contains a 510(k) Summary or 510(k) Statement. *Refer to 21 CFR 807.92 and 21 CFR 807.93 for contents of 510(k) Summary and Statement, respectively. Adequacy of the content will be assessed during substantive review.*		☐	☐		
		Comments:					
	5.	Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k). *See recommended format (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).*		☐	☐		
		Comments:					
	6.	Submission is a Class III 510(k) Device.		☐		☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		Select "N/A" only if submission is not a Class III 510(k).					
		a.	Contains Class III Summary and Certification *See recommended content (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142662.htm). Select "N/A" only if submission is not a Class III 510(k).*	☐	☐	☐	
		Comments:					
	7.	Submission contains clinical data. *Select "N/A" if the submission does not contain clinical data. If "N/A"is selected, parts a and b below are omitted from the checklist.*		☐		☐	
		a.	Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each covered clinical study included in the submission. *Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the Guidance for Industry-Financial Disclosures by Clinical Investigators.*	☐	☐	☐	
		b.	Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. *Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j)*	☐	☐	☐	
		Comments:					
	8.	The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device. *Prior submissions (or no prior submissions) for this device should be included in Section F (prior related submissions) of the CDRH Premarket Review Submission Cover Sheet form (Form 3514). This information may also be included in the Cover Letter (i.e., as*		☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions).					
		a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed. *To address this criterion, it is recommended that the submission include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that adequacy of how the feedback was addressed will be assessed during the substantive review.* *Select "N/A" if the submitter states there were no prior submissions.*	☐	☐	☐	
		Comments:					
B.	**Device Description**						
	9.	The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device. *If "N/A"is selected, parts a and b below are omitted from the checklist.*		☐		☐	
		a.	The submission addresses device description recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes device description information that addresses relevant mitigation measures set forth in a special	☐	☐	☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
			controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*				
		Comments:					
	10.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).		☐	☐		
		Comments:					
	11.	The submission includes descriptive information for the device, including the following:					
		a.	A description of the principle of operation or mechanism of action for achieving the intended effect.	☐	☐		
		b.	A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☐	☐		
		c.	A list and description of each device for which clearance is requested. *Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, various sizes, etc.*	☐	☐	☐	
		d.	Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the	☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
			device). *In lieu of engineering drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.*				
		Comments:					
	12.	Device is intended to be marketed with multiple components, accessories, and/or as part of a system. *Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system. If "N/A"is selected, parts a-c below are omitted from the checklist.*		☐		☐	
		a.	Submission includes a list of all components and accessories to be marketed with the subject device.	☐	☐		
		b.	Submission includes a description (as detailed in item 11a., 11b., and 11d. above) of each component or accessory. *Select "N/A" if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.*	☐	☐	☐	
		c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance **AND** A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.	☐	☐		
		Comments:					
C.	**Substantial Equivalence Discussion**						
	13.	Submitter has identified a predicate device(s), including the following information:					
		a.	Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device).	☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
			For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm).*				
		b.	The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	☐	☐		
		Comments:					
	14.	Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.*					
		a.	Indications for use *If there are no differences between the subject device and the predicate(s) with respect to indications and intended use, this should be explicitly stated.*	☐	☐		
		b.	Technology, including features, materials, and principles of operation *Examples of technological characteristics include, but are not limited to design, features, materials, energy source, and principle of operation.* *FDA recommends a tabular format for comparing technological characteristics. Any characteristic that is the same as the predicate(s) should be explicitly stated. Differences in technological characteristics should be identified and a rationale provided why they do not raise*	☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
			different questions of safety and effectiveness.				
		Comments:					
D.	**Proposed Labeling (see also 21 CFR parts 801 and 809 as applicable)**						
	15.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).		☐	☐		
		a.	Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided)	☐	☐		
		b.	Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☐	☐		
		Comments:					
	16.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)		☐	☐		
		Comments:					
	17.	Labeling includes the prescription statement (see 21 CFR 801.109(b)(1)) or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements"). *Select "N/A" if not indicated for prescription use.*		☐	☐	☐	
		Comments:					
	18.	The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding labeling that is applicable to the subject		☐		☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		device. *If "N/A"is selected, parts a and b below are omitted from the checklist.*					
		a.	The submission addresses labeling recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes labeling information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		Comments:					
	19.	If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. Select "N/A" if not an in vitro diagnostic device.		☐	☐	☐	
		Comment:					
E.	**Sterilization**					☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**	**Yes**	**No**	**N/A**	***Page #**
If an in vitro diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.				
Submission states that the device, and/or accessories, and/or components are: (*one of the below must be checked*) ☐ Provided sterile, intended to be single-use ☐ Requires processing during its use-life ☐ Non-sterile when used (and no processing required) ☐ Information regarding the sterility status of the device is not provided (if this box is checked, please also check one of the two boxes below) ☐ Sterility status not needed for this device (e.g., software-only device) ☐ Sterility status needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "non-sterile when used" or "not provided and not needed" is selected, the sterility-related criteria below are omitted from the checklist.* *If information on sterility status is not provided, and it is needed or the need for this information is unclear, select "No."* *The "Requires processing during its use-life" option refers to devices falling into one of the four categories below:* • *Supplied sterile and requires reprocessing prior to subsequent patient use* • *Supplied non-sterile and requires user to process the device for initial use, as well as to reprocess the device after each use* • *Reusable medical device (single-user) reprocessed between each use* • *Single-use medical devices initially supplied as non-sterile to the user, and requiring the user to process the device prior to its use* *Please refer to the guidance document titled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" for additional information.*		☐		
Comments:				
20. Assessment of the need for cleaning and subsequent disinfection or sterilization information.				
a. Identification of device, and/or accessories, and/or	☐	☐	☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
			components that are provided sterile. *Select "N/A" if no part of the device, accessories, or components is provided sterile.*				
		b.	Identification of device, and/or accessories, and/or components that are end user sterilized or disinfected. *Select "N/A" if no part of the device, accessories, or components is end user sterilized or disinfected.*	☐	☐	☐	
		c.	Identification of device, and/or accessories, and/or components that are reusable. *Select "N/A" if no part of the device, accessories, or components is reusable.*	☐	☐	☐	
		Comments:					
	21.	If the device, and/or accessory, and/or a component is provided sterile: *Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-f below.*				☐	
		a.	Sterilization method is stated for each component (including dose for radiation sterilization)	☐	☐		
		b.	A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date). *Note: the sterilization validation report is not required.*	☐	☐		
		c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits. *Select "N/A" if not sterilized using chemical sterilants.*	☐	☐	☐	
		d.	Sterility Assurance Level (SAL) stated	☐	☐		
		e.	Submission includes description of packaging	☐	☐		
		f.	For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]). *Select "N/A" if not labeled "non-pyrogenic."*	☐	☐	☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**					**Yes**	**No**	**N/A**	***Page #**
		Comments:						
	22.	If the device, and/or accessory, and/or a component is reusable or end user sterilized or disinfected: *Select "N/A" if no part of the device, accessories, or components are reusable or end user sterilized or disinfected, otherwise complete a-d below.*					☐	
		a.	Cleaning method is provided in labeling for each device, and/or accessory, and/or component. *Select "N/A" if not reusable and does not need cleaning prior to disinfection or sterilization*		☐	☐	☐	
		b.	Disinfection method is provided in labeling for each device, and/or accessory, and/or component. *Select "N/A" if not disinfected (i.e., undergoes terminal sterilization) prior to use*		☐	☐	☐	
		c.	Sterilization method is provided in labeling for each device and/or accessory, and/or component. *Select "N/A" if not sterilized (i.e., undergoes disinfection) prior to use*		☐	☐	☐	
		d.	Device types in this submission are listed in Appendix E of the FDA's guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling." *Device types identified in Appendix E of the reprocessing guidance represent devices posing a greater likelihood of microbial transmission and represent a high risk of infection. Select "N/A" if the device type in the submission is not included in Appendix E of the reprocessing guidance.*		☐		☐	
			i.	If device types in this submission are included in Appendix E of the reprocessing guidance, the submission includes protocols and test reports for validating the reprocessing instructions. *Select "N/A" if the device type in the submission is not included in Appendix E of the reprocessing guidance.*	☐	☐	☐	
		Comments:						
	23.	The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific			☐		☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		regulation regarding sterility and/or reprocessing that is applicable to the subject device *If "N/A"is selected, parts a and b below are omitted from the checklist.*					
		a.	The submission addresses sterility and/or reprocessing recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes sterility and/or reprocessing information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		Comments:					
F.	**Shelf-Life**						
	24.	Proposed shelf life/ expiration date stated **OR** Statement that shelf-life is not applicable because of low		☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
		likelihood of time-dependent product degradation				
		Comments:				
	25.	For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf-life. *Select "N/A" if the device is not provided sterile.*	☐	☐	☐	
		Comments:				
	26.	Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	☐	☐		
		Comments:				
G.	**Biocompatibility** *If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*				☐	
	Submission states that there: (*one of the below must be checked*) ☐ Are direct or indirect patient-contacting components ☐ Are no direct or indirect patient-contacting components ☐ Information regarding patient contact status of the device is not provided (if this box checked, please also check one of the two boxes below) ☐ Patient contact information not needed for this device (e.g., software-only device) ☐ Patient contact information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "are no" or "not provided and not needed" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information on the patient-contact status is not provided, and contact information is needed or its*			☐		

			Yes	No	N/A	*Page #
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**						
	contact status is unclear, select "No." *An example of a direct patient-contacting device would be an implant that has direct contact with patient tissues during use. An example of an indirect patient-contacting device would be fluid entering the patient's body following passing through device/device components not in direct contact with the patient.*					
	Comments:					
	27.	Submission includes a list identifying each patient-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	☐	☐		
		Comments:				
	28.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration) for each patient-contacting device component (e.g., implant, delivery catheter).	☐	☐		
		Comments:				
	29.	Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	☐	☐		
		Comments:				
H.	**Software**					
	Submission states that the device: (*one of the below must be checked*) ☐ Does contain software/firmware ☐ Does not contain software/firmware ☐ Information on whether device contains software/firmware is not provided (if this box checked, please also check one of the two boxes below)			☐		

			Yes	No	N/A	*Page #
		Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				
		☐ Software/firmware information not needed for this device (e.g., surgical suture, condom) ☐ Software/firmware information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not contain" or "not provided and not needed" is selected, the software-related criteria below are omitted from the checklist. If information on software is not provided, and this information is needed or the need is unclear, select "No."*				
		Comments:				
	30.	Submission includes a statement of software level of concern and rationale for the software level of concern	☐	☐		
		Comments:				
	31.	All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale). *Note: This element is also applicable to non-internally generated or off-the-shelf (OTS) software used in the device.*	☐	☐		
		Comments:				
I.	**Electrical Safety and EMC**					
		Electrical Safety: Submission states that the device: (*one of the below must be checked*) ☐ Does require electrical safety evaluation ☐ Does not require electrical safety evaluation ☐ Information on whether device requires electrical safety evaluation not provided (if this box checked, please also check one of the two boxes below) ☐ Electrical safety information not needed for this device (e.g., surgical		☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
		suture, condom) ☐ Electrical safety information needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not require" or "not provided and not needed" is selected, the electrical safety criteria below are omitted from the checklist. If information on electrical safety is not provided, and it is needed or the need for this information is unclear, select "No."*				
		Comments:				
	32.	Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, a device-specific standard). **<u>OR</u>** Submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☐	☐		
		Comments:				
	EMC: Submission states that the device: (*one of the below must be checked*) ☐ Does require EMC evaluation ☐ Does not require EMC evaluation ☐ Information on whether device requires EMC evaluation not provided (if this box checked, please also check one of the two boxes below) ☐ EMC information not needed for this device (e.g., surgical suture, condom) ☐ EMC information needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not require" or "not provided and not needed" is selected, the EMC criteria below are omitted from the checklist. If information on EMC is not*			☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	provided, and it is needed or the need for this information is unclear, select "No."						
	Comments:						
	33.	Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, a device-specific standard). **OR** Submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).		☐	☐		
		Comments:					
J.	**Performance Data General** *If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.*					☐	
	Comments:						
	34.	Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions. *Full test reports provided for all completed tests/evaluations (e.g., bench evaluations, comparative performance tests, etc.). Select "N/A" if the submission does not include performance data.*		☐	☐	☐	
		a.	Submission includes an explanation of how the data generated from each test report supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.). *Select "N/A" if the submission does not include performance data.*	☐	☐	☐	
		Comments:					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	35.	The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding performance data that is applicable to the subject device *If "N/A"is selected, parts a and b below are omitted from the checklist.*		☐		☐	
		a.	The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes performance data that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		Comments:					
	36.	If literature is referenced in the submission, submission includes: *Select "N/A" if the submission does not reference literature. If "N/A"is selected, parts a and b below are omitted from the*				☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		checklist. *Note that the applicability of the referenced article to support a substantial equivalence finding should be assessed during the substantive review; only the presence of a discussion is required to support acceptance.*					
		a.	Legible reprints or a summary of each article.	☐	☐		
		b.	Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	☐	☐		
		Comments:					
	37.	For each completed animal study, the submission provides the following: *Select "N/A" if no animal study was conducted. If "N/A"is selected, parts a-c below are omitted from the checklist. Note that this section does not address biocompatibility evaluations, which are assessed in Section G of the checklist.*				☐	
		a.	Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120	☐	☐		
		b.	Submission includes final study report which includes all elements outlined in 21 CFR 58.185	☐	☐		
		c.	Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	☐	☐		
		Comments:					
K.	**Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))**						
	Submission indicates that device: (*one of the below must be checked*) ☐ Is an in vitro diagnostic device ☐ Is not an in vitro diagnostic device *If "is not" is selected, the performance data-related criteria below are omitted from the checklist.*						

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	38.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:					
		a.	Precision/reproducibility	☐	☐	☐	
		b.	Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff.	☐	☐	☐	
		c.	Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).	☐	☐	☐	
		d.	Analytical specificity	☐	☐	☐	
		Comments:					
	39.	The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulations regarding performance data that is applicable to the subject device. *If "N/A"is selected, parts a and b below are omitted from the checklist.*		☐	☐	☐	
		a.	The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes performance data that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device.	☐	☐	☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
			OR The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*				
		Comments:					

Decision: Accept_____ Refuse to Accept_____

If Accept, notify the applicant

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

*Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

Appendix C

Contains Nonbinding Recommendations

Acceptance Checklist for Special 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k)#: K **Date Received by DCC:**

Lead Reviewer:

Branch: **Division:** **Center/Office:**

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

Special 510(k) Criteria

The submission should not be reviewed as a Special 510(k) if "No" is selected for any of the 4 criteria below. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.

		Yes	No
1.	**510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.**	☐	☐
	Comments:		
2.	**Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).**	☐	☐
	Comments:		
3.	**Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).**	☐	☐
	Comments:		
4.	**The submission includes only summary-level information (i.e., NO test reports with performance data).** *Note that if performance data are provided and are conducted under design validation (21 CFR 820.30(g)), for example, to demonstrate continued conformance with a special control or recognized standard, then a Special 510(k) may be appropriate.*	☐	☐
	Comments:		

Does the submission meet all 4 criteria above?

☐ Yes, submission meets criteria for a Special 510(k). Continue checklist below.

☐ No, submission does not meet criteria for a Special 510(k). Discontinue this RTA checklist, convert to a Traditional and apply the Traditional checklist.

Organizational Elements Failure to include these items should not result in an RTA designation.				
***Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**		**Yes**	**No**	***Page #**
1.	Submission contains a Table of Contents.	☐	☐	
2.	Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.).	☐	☐	
3.	All pages of the submission are numbered. *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☐	☐	
4.	Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special) *If type of 510(k) is not designated, review as a Traditional 510(k).*	☐	☐	
Comments:				

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during the RTA review.
-
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**	**Yes**	**No**	**N/A**	***Page #**

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
A.	**Administrative**						
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.).		☐	☐		
		Comments:					
	2.	Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
		a.	Device trade/proprietary name	☐	☐		
		b.	Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	☐	☐		
		Comments:					
	3.	Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") *See recommended format (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).*		☐	☐		
		Comments:					
	4.	Submission contains a 510(k) Summary or 510(k) Statement. *Refer to 21 CFR 807.92 and 21 CFR 807.93 for contents of 510(k) Summary and Statement, respectively. Adequacy of the content will be assessed during substantive review.*		☐	☐		
		Comments:					
	5.	Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k). *See recommended format (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).*		☐	☐		
		Comments:					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	6.	Submission is a Class III 510(k) Device. *Select "N/A" only if submission is not a Class III 510(k).*		☐		☐	
		a.	Contains Class III Summary and Certification *See recommended content (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142662.htm). Select "N/A" only if submission is not a Class III 510(k).*	☐	☐	☐	
		Comments					
	7.	The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device. *Prior submissions (or no prior submissions) for this device should be included in Section F (prior related submissions) of the CDRH Premarket Review Submission Cover Sheet form (Form 3514). This information may also be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions).*		☐	☐		
		a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed. *To address this criterion, it is recommended that the submission include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that adequacy of how the feedback was addressed will be assessed during the substantive review.* *Select "N/A" if the submitter states there were no prior submissions.*	☐	☐	☐	
		Comments:					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
B.	**Device Description**						
	8.	The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device. *If "N/A"is selected, parts a and b below are omitted from the checklist.*		☐		☐	
		a.	The submission addresses device description recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes device description information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		Comments:					
	9.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with		☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		the device description in the labeling).					
		Comments:					
	10.	The submission includes descriptive information for the device, including the following:					
		a.	A description of the principle of operation and mechanism of action for achieving the intended effect.	☐	☐		
		b.	A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☐	☐		
		c.	A list and description of each device for which clearance is requested. *Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, various sizes, etc.*	☐	☐	☐	
		d.	Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device). *In lieu of engineering drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.*	☐	☐		
		Comments:					
	11.	A description of all device modification(s) including rationale for each modification.		☐	☐		
		Comments:					
	12.	Device is intended to be marketed with multiple components, accessories, and/or as part of a system. *Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system. If*		☐		☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		"N/A"is selected, parts a-c below are omitted from the checklist.					
		a.	Submission includes a list of all components and accessories to be marketed with the subject device.	☐	☐		
		b.	Submission includes a description (as detailed in item 10a., 10b., and 10d. above) of each component or accessory. *Select "N/A" if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.*	☐	☐	☐	
		c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance **AND** A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.	☐	☐		
		Comments:					
C.	**Substantial Equivalence Discussion**						
	13.	Submitter has identified a predicate device(s), including the following information:					
		a.	Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm)* .	☐	☐		
		b.	The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	☐	☐		
		Comments:					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	14.	Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.*					
		a.	Indications for use *If there are no differences between the subject device and the predicate(s) with respect to indications and intended use, this should be explicitly stated.*	☐	☐		
		b.	Technology, including features, materials, and principles of operation *Examples of technological characteristics include, but are not limited to design, features, materials, energy source, and principle of operation.* *FDA recommends a tabular format for comparing technological characteristics. Any characteristic that is the same as the predicate(s) should be explicitly stated. Differences in technological characteristics should be identified and a rationale provided why they do not raise different questions of safety and effectiveness.*	☐	☐		
D.	**Design Control Activities**						
	15.	Design Control Activities Summary includes all of the following:					
		a.	Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components **AND** the results of the analysis	☐	☐		
		b.	Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria	☐	☐		
		c.	Declaration of conformity with design controls. All 3 below must be present to answer "Yes."	☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
			i. Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met. ii. Statement that manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30. iii. Statement is signed by the individual responsible for these activities.				
		Comments:					
E.	**Proposed Labeling (see also 21 CFR parts 801 and 809 as applicable)**						
	16.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).		☐	☐		
		a.	All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified.	☐	☐		
		Comments:					
	17.	Statement that the intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).		☐	☐		
		Comments:					

Decision: Accept_____ Refuse to Accept_____

If Accept, notify the applicant

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

*Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.