Draft Guidance for Industry and Food and Drug Administration Staff

---

Refuse to Accept Policy for 510(k)s

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.
Document issued on: August 13, 2012

You should submit comments and suggestions regarding this draft document within **45** days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

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 301-827-1800.

When final, this document will supersede the following guidance documents: Center for Devices and Radiological Health's 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.

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

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-827-8149 to receive a hard copy. 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), 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, by telephone, 1-800-835-4709 or 301-827-1800, by email, ocod@fda.hhs.gov, or from the Internet at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.

Draft Guidance for Industry and Food and Drug Administration Staff

---

Refuse to Accept Policy for 510(k)s

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

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 updates two existing guidance documents entitled "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. Upon issuance as a final guidance document, this guidance will replace those documents.

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 sponsors of 510(k) notifications and allowing FDA to appropriately concentrate resources on complete submissions.

Therefore, we have modified our 510(k) Refuse to Accept (RTA) policy to include an early review against specific acceptance criteria and to inform the submitter within the first 15

[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).

calendar days after receipt of the submission if the submission is administratively complete, or if not, 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 encourages all submitters to provide an electronic copy (eCopy) in place of one of the two hard copies of the 510(k) submission.[2] For additional information regarding formatting eCopies for submissions sent to the Center for Devices and Radiological Health (CDRH), please refer to our website for guidelines for submitting:

- General information (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm) and
- Clinical data (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm136377.htm).

For additional information regarding formatting eCopies and submitting hard copies for submissions sent to CBER, please refer to:

- "Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format-General Considerations" (http://www.fda.gov/RegulatoryInformation/Guidances/ucm124737.htm) and
- "CBER SOPP8110: Submission of Paper Regulatory Applications to CBER" (http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm079467.htm).

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.

[2] FDA has issued draft guidance ("eCopy Program for Medical Device Submissions," available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf) to implement section 1136 of the FDASIA, which added Section 745A(b) of the FD&C Act, and provides statutory authority to require eCopy. When final, this guidance will represent the Agency's thinking on this topic.

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/ucm084365.htm).

The previous guidances relating to 510(k) RTA policy and the checklist currently used for acceptance review have focused on defining broad issues or principles. Additionally, the previous checklist deals largely with administrative elements but it does not address specific content that is essential for 510(k) review. As a result, FDA accepts many inadequate submissions for review and FDA staff invests significant time in constructing extensive letters requesting all of the additional information needed to conduct a substantive review. This approach is an inefficient use of resources and frequently lengthens 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 this guidance document is 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 Acceptance Checklists for traditional, special, and abbreviated 510(k) submissions, which FDA staff will use during the acceptance review process.

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.

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 online; see "Premarket Notification [510(k)] Review Fees" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134566.htm).

Pre-submission Interaction

Prior to interacting with review staff, submitters should consult CDRH's Division of Small Manufacturers, International and Consumer Assistance (DSMICA) or CBER's Manufacturers Assistance and Technical Training Branch for general information regarding the 510(k) regulations. 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 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 Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff."[3] (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm).

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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm?utm_campaign=Google2&utm_source=fdaSearch&utm),
- Other applicable CDRH device-specific and cross-cutting guidance documents, (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm), and
- CDRH's Device Advice (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm).

[3] Once finalized, this guidance will represent the Agency's current thinking on this topic.

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. The acceptance review should be conducted and completed within 15 calendar days of FDA receiving the 510(k) notification.

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 letters, 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 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).

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

Upon receipt of the newly submitted information, FDA staff should conduct the acceptance screening again following the same procedure within 15 calendar days of receipt of the new information. 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).

[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.

When a submission is found acceptable, FDA staff should notify the submission contact person in writing that the 510(k) has been accepted and begin a substantive review of the submission to determine substantial equivalence. Should FDA fail to complete the acceptance review within 15 calendar days, the submission should be considered accepted, the submitter should be notified in writing, and FDA should commence with 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 designated RTA. The FDA review clock also would not start if we receive unsolicited amendments during the acceptance review period. Once an application is "Accepted," the FDA review clock begins as of the date of receipt of the most recent submission or amendment that made the 510(k) complete (even if FDA later requests information that should have been requested during acceptance review).

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.

---

[5] In the case of extenuating circumstances such as 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) (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)],).

Staff should consider the submitter's justifications for any alternative approaches

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.[7] 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. See Acceptance Review section below for examples and further explanation.

The submitter should review device-specific and cross-cutting guidance documents, applicable recognized standards, and applicable regulations.

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. 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).

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. 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,[8] FDA staff should promptly notify the submitter using proper administrative procedures.

The preliminary questions are:

[7] The presence of a justification is particularly relevant in the acceptance review stage while the adequacy of such justifications to justify the omission of certain information falls within the scope of the substantive review phase.

[8] 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 draft 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). Once this guidance is final, at least one copy of the submission will be required to be an eCopy. 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?**

   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 Office 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 application with the appropriate Center?**

   If the application 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) team leader should consult with the CDRH Jurisdictional Officer or the CBER Office 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 application is not subject to CDRH review, or the 510(k) is submitted to CBER and CBER staff determines that the application is not subject to CBER review, the 510(k) review team should stop the review and notify the applicant.

3. **Is a 510(k) the appropriate regulatory submission?**

   Staff should determine whether a 510(k) is the appropriate regulatory submission. If a 510(k) is not appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), staff should make this determination during the acceptance review and notify the submitter of the determination.

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

   If there is a pending PMA for the same device, the submitter should withdraw either the 510(k) or the PMA. The review team should consult division management and other Center resources to determine the appropriate action.

5. **If clinical studies have been submitted, is the submitter the subject of the Application Integrity Policy (AIP)?**[9]

   The lead reviewer should refer to the AIP list (http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm

[9] When data in a pending application 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.)

). If the applicant is on the list, the reviewer should consult the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action.

The Checklist – 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.

Elements of a Complete Submission (RTA Items)
The objective criteria in this checklist 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 new 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 to 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 inapplicable.

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 sponsor should follow the recommendations included in that document, or the sponsor should provide a rationale for addressing the scientific issues discussed in the guidance document using an alternative approach in order to meet the applicable statutory and regulatory criteria. In the absence of the recommended information and without a supporting rationale for an alternative approach, the submission should be considered incomplete and not accepted. If special controls have been identified for the device, those controls should be addressed in order for the submission to be accepted. Note, however, that the special controls *must* be followed in order for the device to be considered in Class II and therefore to support a finding of substantial equivalence.

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.), 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 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. 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, 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, FDA may determine that the results of a particular test are not 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 need for additional justification should be communicated to the submitter 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 contains all descriptive information recommended 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.

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), FDA will notify the contact person designated in the 510(k) submission of the conversion and the rationale for the conversion. Additionally, 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 acceptance review will proceed with the traditional checklist.

If a 510(k) designated as a special 510(k) qualifies as a special 510(k), but the submission includes performance data, FDA should offer the submitter two options: (1) the data can be removed from the 510(k) and staff will proceed with the special 510(k) checklist, or (2) the 510(k) can be converted to a traditional 510(k) and the submitter will provide any other missing information needed for a traditional 510(k) in order to be accepted for substantive review.

Contains Nonbinding Recommendations
Draft - Not for Implementation

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.

510(k) Number: _____ Date Received: _____

Lead Reviewer Name: _____ Branch: _____ Division: _____ Office: _____

Preliminary Questions		
Answers in the shaded blocks indicate consultation with Center advisor is needed.	**Yes**	**No**
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 Office 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 application 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 application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."		
Comments:		
3. Is a 510(k) the appropriate regulatory 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:		
4. Is there a pending PMA for the same device with the same indications for use? If there is a pending PMA for the same device, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		
Comments:		
5. 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 - BIMO) 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 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 3 is no, the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 4 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 5 is "Yes," then contact CDRH/OC/DBM – BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Organizational Elements

Failure to include these items alone generally should not result in an RTA designation

	Yes	No
a. Submission contains Table of Contents		
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)		
c. 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…).*		
d. Type of 510(k) is identified– traditional, abbreviated, or special *If type of 510(k) is not designated, review as a traditional*		
Comments:		

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
A.	**Administrative**					
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc,)		☐		☐
		Comments:				
	2.	510(k) cover letter that identifies:		☐		☐
		a.	Device trade name or proprietary name	☐		☐
		b.	Device common name	☐		☐
		c.	Device class and panel	☐		☐
		Comments:				
	3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 801.109) *Submitter should use format appropriate for the reviewing Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request the correct format during substantive review.*		☐		☐
		Comments:				
	4.	Submission contains 510(k) Summary or 510(k) Statement *Either a) or b) must be answered "Yes" to be considered complete. Identify any missing element(s) as Comments.*		☐		☐
		a.	Summary contains all elements per 21 CFR 807.92 *See also 510(k) Summary Checklist*	☐	☐	☐
		b.	Statement contains all elements per 21 CFR 807.93	☐	☐	☐
		Comments:				

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
	5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format*		☐		☐
		Comments:				
	6.	Submission contains Class III Summary and Certification *See recommended content* *Form should be signed by a responsible person of the firm, not a consultant. CDRH is not currently able to accept a digital signature.* *"N/A" only if submission is not a Class III 510(k).*		☐	☐	☐
		Comments:				
	7.	If submission relies upon a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (FDA Form 3654) or includes detailed information about how and the extent to which the standard has been followed *There should be a completed form for each referenced national or international standard.* *"N/A" only if submission does not reference any standards.*		☐	☐	☐
		Comments:				
	8.	Does submission contain clinical data? *Select "N/A" for this item and 8.a. and 8.b. if the submission does not contain clinical data. If submission does contain clinical data, parts a. and b. must be answered "yes" for the 510(k) to be complete.*		☐	☐	
		a.	Submission includes Financial Certification/Disclosure Statement	☐	☐	☐

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
		b.	Submission includes Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B))	☐	☐	☐
		Comments:				
	9.	If this is a bundled submission, the submission has been appropriately bundled [i.e., the correct user fee(s) have been paid for the devices/indications (section 738 of the FD&C Act)] *See* Guidance for Industry and FDA Staff: Bundling Multiple Devices or Multiple Indications in a Single Submission. *"N/A" if not a bundled submission*		☐	☐	☐
		Comments:				
	10.	The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions.		☐		☐
		a.	If there were prior submissions: within current submission, the sponsor has identified where in the current submission any issues related to substantial equivalence outlined in prior communications are addressed.	☐	☐	☐
		Comments:				
B.	**Device Description**					
	11.	If there is a device-specific guidance document or special controls applicable to this submission, documentation has been provided to establish that the submitter has followed the recommendations in the applicable device-specific guidance document or special controls		☐	☐	☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
		regarding the device description or otherwise met the applicable statutory or regulatory criteria through an alternative approach. *Select "No" if the submission does not include a rationale for any omitted information or any alternative approaches.* *Select "N/A" if there is no device-specific guidance document*				
		Comments:				
	12.	All descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
		a.	A description of the principle of operation and mechanism of action for achieving the intended therapeutic/diagnostic effect.	☐		☐
		b.	A description of all 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 model for which clearance is requested. *Select "N/A" if there is only one model.*	☐	☐	☐
		Comments:				
	13.	Where applicable, submission contains engineering drawing(s), schematics, illustrations and/or figures of the device that are clear and legible, and include dimensions		☐	☐	☐
		a.	If engineering drawings, schematics, illustrations and/or figures are provided, one is provided for each model to be marketed	☐	☐	☐
		Comments:				

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
	14.	If 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.*			☐	
		a.	A description (as detailed in item 12.a. and b. and 13 above) is provided for each component or accessory.	☐		☐
		b.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. *Select "N/A" if the submission states that the component(s)/ accessory(ies) do not have a prior 510(k) clearance.*	☐	☐	☐
		Comments:				
C.	**Substantial Equivalence Discussion**					
	15.	Submitter has identified a predicate(s) device		☐		☐
		a.	Predicate's 510(k) number, trade name, and model number (if applicable) provided	☐		☐
		b.	The identified predicate(s) is consistent throughout the submission (i.e., 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:				
	16.	Submission includes a comparison of the following for the predicate(s) and subject device				
		a.	Indications for use	☐		☐
		b.	Technology, including features, materials, and principles of operation	☐		☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
		Comments:				
	17.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., do not constitute a new intended use, affect safety or effectiveness, or raise different questions of safety and effectiveness) (see section 513(i)(1)(A) of the FD&C Act) *If there is no difference between the subject and predicate(s) with respect to indications for use or technology, this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences. Note that due to potential differences in manufacturing that may not be known to the submitter, no identified differences does not necessarily mean that no performance testing is needed.*		☐	☐	☐
		Comments:				
D.	**Proposed Labeling (see also 21 CFR part 801)**					
	18.	Submission includes proposed labels, labeling (e.g., instructions for use, package insert, operator's manual), and advertisements that describe the device, its intended use, and the directions for use				
		a.	Indications for use stated in labeling (21 CFR 801.61) and identical to IFU form and 510(k) Summary (if applicable)	☐		☐
		b.	Directions for use included (including relevant hazards, warnings, precautions, contraindications), including directions for layperson (see 21 CFR 801.5) unless submission states that device qualifies for exemption per 21 CFR 801 Subpart D.	☐		☐
		Comments:				

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
	19.	If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements] *Select "N/A" if not indicated for prescription use.*		☐	☐	☐
		Comments:				
	20.	General labeling provisions				
		a.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)	☐		☐
		b.	Labeling includes device common or usual name (21 CFR 801.61)	☐		☐
		Comments:				
	21.	If there is a device-specific guidance, special controls, or regulation, the provided labeling establishes that the submitter has followed the recommendations in the applicable guidance document, special controls, or regulation, or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no device-specific guidance or regulation.*		☐	☐	☐
		Comments:				
	22.	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.*		☐	☐	☐
E.	**Performance Data – General**					
	Submission: (*one of the below must be checked*) ☐ does ☐ does not contain performance data. *If "does not" is selected, the performance data-related criteria below are omitted from the checklist.*					

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.		**Yes**	**N/A**	**No**
	Comments:				
	23.	Full test report is provided for each completed test to explain how the data generated from the test supports a finding of substantial equivalence. (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, and conclusions.)	☐		☐
		Comments:			
	24.	Submission includes document to establish that the submitter has followed the recommendations for performance data outlined in the applicable device-specific guidance document or special controls, or otherwise met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no device-specific guidance document.*	☐	☐	☐
		Comments:			
	25.	If literature was used as performance data, submission includes reprints or a summary of each article, and a discussion as to how each article is applicable to support the substantial equivalence of the subject device to the predicate.	☐	☐	☐
		Comments:			
	26.	If an animal study was conducted, *Select "N/A" if no animal study was conducted.*		☐	
		a. Submission includes a study protocol and final study report to explain how the data generated from the study supports a finding of substantial equivalence. (A final study report includes a contributing scientist report for each preclinical endpoint of evaluation within the protocol, such as performance/handling, in life, imaging, pathology, etc.)	☐		☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
		b.	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:				
F.	**Sterilization**					
	Submission states that the device and/or accessories are: (*one of the below must be checked*) ☐ sterile ☐ non-sterile but sterilized by the end user ☐ non-sterile when used This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "non-sterile when used" is selected, the sterility-related criteria below are omitted from the checklist.* *If information regarding the sterility status of the device is not provided, select "No."*					☐
	Comments:					
	27.	Assessment of the need for sterilization information				
		a.	Identification of device, and/or accessories, and/or components that are provided sterile.	☐	☐	☐
		b.	Identification of device, and/or accessories, and/or components that are end user sterilized	☐	☐	☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
		c.	Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided.	☐	☐	☐
		Comments:				
	28.	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 parameters such as dry time for steam sterilization, radiation dose, etc.)	☐		☐
		b.	A description of method to validate the sterilization cycle (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided	☐		☐
		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.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package)	☐		☐
		e.	Sterility Assurance Level (SAL) stated	☐		☐
		f.	If device is blood-contacting, a permanent implant, or contacts cerebrospinal fluid, or device is labeled "non-pyrogenic," submission contains a description of the endotoxin method used to make a determination (e.g., LAL), endotoxin release specification (e.g., 20 EU/device), and a rationale for the specification.	☐	☐	☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
			Select "N/A" if device is not blood-contacting, not a permanent implant, does not contact cerebrospinal fluid, and is not labeled "non-pyrogenic." Select "N/A" if a rationale for omission is provided.			
		Comments:				
	29.	All sterility information provided as recommended in the following guidance documents or special controls, or information provided indicating the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach: *Either "a" or "b" must be answered "Yes" to be considered complete.*				
		a.	Device-specific guidance document or special controls *Select "N/A" if no device-specific guidance document.*	☐	☐	☐
		b.	Cross-cutting guidance document (for more information see "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile") *Select "N/A" if device-specific guidance followed instead.*	☐	☐	☐
		Comments:				
G.	**Shelf Life**					
	30.	If the device is provided sterile or the device is provided non-sterile and storage conditions (i.e., aging) could impact device safety or effectiveness, address the following: *Select "N/A" if the device is not provided sterile and the submitter states that storage conditions could not affect device safety or effectiveness.*			☐	
		a.	Proposed shelf life/expiry date stated	☐		☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
		b.	Submission includes description of shelf life validation method(s) used to ensure device performance and sterility, as applicable, remain substantially equivalent to that of the predicate device throughout the stated shelf life.	☐		☐
		Comments:				
H.	**Biocompatibility**					
	Submission states that there: (*one of the below must be checked*) ☐ are ☐ are not direct or indirect (e.g., through fluid infusion) patient-contacting components. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "are not" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information regarding whether the device is patient-contacting is not provided, select "No."*					☐
	Comments:					
	31.		Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	☐		☐
		Comments:				
	32.		Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)	☐		☐
		Comments:				

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.		**Yes**	**N/A**	**No**
	33.	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).	☐		☐
I.	**Software**				
	Submission states that the device: (*one of the below must be checked*) ☐ does ☐ does not contain software. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not" is selected, the software-related criterion is omitted from the checklist. If information regarding whether the device contains software is not provided, select "No."*				☐
	Comments:				
	34.	All appropriate categories of software verification and validation documentation provided based on stated level of concern, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submitter has provided documentation that it has otherwise met the applicable statutory or regulatory criteria through an alternative approach.	☐		☐
		Comments:			

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.		**Yes**	**N/A**	**No**
J.	**EMC and Electrical Safety**				
	Submission states that the device: (*one of the below must be checked*) ☐ does ☐ does not require EMC and Electrical Safety evaluation. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not" is selected, the EMC-related and Electrical Safety-related criteria below are omitted from the checklist. If information regarding whether the device requires EMC and Electrical Safety evaluation is not provided, select "No."*				☐
	Comments:				
	35.	Submission includes evaluation of electrical safety per IEC 60601-1 or equivalent FDA-recognized standard and if applicable, the device-specific standard OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and information indicating that these methods/standards otherwise meet applicable statutory and regulatory requirements.	☐		☐
		Comments:			
	36.	Submission includes evaluation of electromagnetic compatibility per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and information indicating that these methods/standards otherwise meet applicable	☐		☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
		statutory and regulatory requirements.				
		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 ☐ is not an in vitro diagnostic device (IVD). *If "is not" is selected, the performance data-related criteria below are omitted from the checklist.*					
	Comments:					
	37.	Submission includes the following analytical studies, including associated protocols and line data:				
		a.	Precision/reproducibility (at least 3 sites generally necessary)	☐	☐	☐
		b.	Accuracy (includes linearity, assay cut-off, method comparison or comparison to clinical outcome, matrix comparison, reference range, and stability protocol and acceptance criteria)	☐	☐	☐
		c.	Sensitivity (detection limits (LoB, LoD, and LoQ))	☐	☐	☐
		d.	Analytical specificity	☐	☐	☐
		Comments:				

Decision: Accept ___ Refuse to Accept ___

If Accept, notify applicant; if Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Team Leader Signature: _____ Date: _____

Supervisory Signature: _____ Date: _____

Contains Nonbinding Recommendations
Draft - Not for Implementation

Refuse to Accept 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.

510(k) Number: _____ Date Received: _____

Lead Reviewer Name: _____ Branch: _____ Division: _____ Office: _____

Preliminary Questions		
Answers in the shaded blocks indicate consultation with Center advisor is needed.	**Yes**	**No**
1. Is the product a device (per section 201(h) of the Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part? 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 Office 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 a combination product, mark "No."		
Comments:		
2. Is the application 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 application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."		
Comments:		
3. Is a 510(k) the appropriate regulatory 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:		

4. Is there a pending PMA for the same device with the same indications for use? If there is a pending PMA for the same device, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to det		
Comments:		
5. 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 - BIMO) 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 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 3 is no, the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 4 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 5 is "Yes," then contact CDRH/OC/DBM – BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's 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	N/A	No
1.	**Submission relies on a device-specific 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-d 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., performance testing to support substantial equivalence) and lists any deviations *Select "No" if the sponsor does not address whether there were deviations.*	☐		☐

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	N/A	No
	Comments:					
2.	**Submission relies on a special control(s), 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., performance testing 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 device-specific standard(s) (See section 514(c)).** *Select "N/A" if submission does not rely on any FDA-recognized standard(s). If "Yes," address parts 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)	☐	☐	☐

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	N/A	No
		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 1, 2, or 3 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 alone generally should not result in an RTA designation*		
	Yes	**No**
a. Submission contains Table of Contents		
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)		
c. 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…).*		
Comments:		

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
A.	**Administrative**					
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc,)		☐		☐
		Comments:				
	2.	510(k) Cover letter that identifies: at a minimum:		☐		☐
		a.	Device trade name or proprietary name	☐		☐
		b.	Device common name	☐		☐
		c.	Device class and panel	☐		☐
		Comments:				

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
	3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 801.109) *Submitter should use format appropriate for the reviewing Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request the correct format during substantive review.*			☐		☐
		Comments:					
	4.	Submission contains 510(k) Summary or 510(k) Statement *Either a) or b) must be answered "Yes" to be considered complete. Identify any missing element(s) as Comments.*			☐		☐
		a.	Summary contains all elements per 21 CFR 807.92 *See also 510(k) Summary Checklist*		☐	☐	☐
		b.	Statement contains all elements per 21 CFR 807.93		☐	☐	☐
		Comments:					
	5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format*			☐		☐
		Comments:					
	6.	Submission contains Class III Summary and Certification *See recommended content* *Form should be signed by a responsible person of the firm, not a consultant. CDRH is not currently able to accept a digital signature.* *"N/A" only if submission is not a Class III 510(k).*			☐	☐	☐
		Comments:					
	7.	If submission relies upon a national or international standard as part of demonstration of substantial equivalence, submission contains			☐	☐	☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
		Standards Data Report for 510(k)s (FDA Form 3654) or includes detailed information about how and the extent to which the standard has been followed. *There should be a completed form for each referenced national or international standard.* *"N/A" only if submission does not reference any standards.*				
		Comments:				
	8.	Does submission contains clinical data? *Select "N/A" for this item and 8.a. and 8.b. if the submission does not contain clinical data. If submission does contain clinical data, parts a. and b. must be answered "yes" for the 510(k) to be complete.*		☐	☐	
		a.	Submission includes Financial Certification/Disclosure Statement	☐	☐	☐
		b.	Submission includes Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)	☐	☐	☐
		Comments:				
	9.	If this is a bundled submission, the submission has been appropriately bundled [i.e., the correct user fee(s) have been paid for the devices/indications (Section 738 FD&C Act)] *See* Guidance for Industry and FDA Staff: Bundling Multiple Devices or Multiple Indications in a Single Submission. *"N/A" if not a bundled submission*		☐	☐	☐
		Comments:				
	10.	The submission identifies related submissions for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior		☐		☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
		not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions.				
		a.	If there are related submissions, within current submission, the sponsor has identified where in the current submission any issues related to substantial equivalence outlined in prior communications are addressed.	☐		☐
		Comments:				
B.	**Device Description**					
	11.	If there is a device-specific guidance document or special controls applicable to this submission, documentation has been provided to establish that the submitter has followed the recommendations in the applicable device-specific guidance document or special controls regarding the device description or otherwise met the applicable statutory or regulatory criteria through an alternative approach. *Select "No" if the submission does not include a rationale for any omitted information or any alternative approaches.* *Select "N/A" if there is no device-specific guidance document*		☐	☐	☐
		Comments:				
	12.	All descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
		a.	A description of the principle of operation and mechanism of action for achieving the intended therapeutic/diagnostic effect.	☐		☐
		b.	A description of all 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.	☐		☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
		c.	A list and description of each model for which clearance is requested. *Select "N/A" if there is only one model.*	☐	☐	☐
		Comments:				
	13.	Where applicable, submission contains engineering drawing(s), schematics, illustrations and/or figures of the device that are clear and legible, and include dimensions		☐	☐	☐
		a.	If engineering drawings, schematics, illustrations and/or figures are provided, one is provided for each model to be marketed	☐	☐	☐
		Comments:				
	14.	If 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.*			☐	
		a.	A description (as detailed in #12.a. and b. and 13 above) is provided for each component or accessory.	☐		☐
		b.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. *Select "N/A" if the submission states that the component(s)/ accessory(ies) do not have a prior 510(k) clearance.*	☐	☐	☐
		Comments:				
C.	**Substantial Equivalence Discussion**					
	15.	Submitter has identified a predicate(s) device		☐		☐
		a.	Predicate's 510(k) number, trade name, and model number (if applicable) provided	☐		☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
		b.	The identified predicate(s) is consistent throughout the submission (i.e., 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:				
	16.	Submission includes a comparison of the following for the predicate(s) and subject device				
		a.	Indications for use	☐		☐
		b.	Technology, including features, materials, and principles of operation	☐		☐
		Comments:				
	17.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., do not constitute a new intended use, affect safety or effectiveness, or raise different questions of safety and effectiveness) (see section 513(i)(1)(A) of the FDA&C Act). *If there is no difference between the subject and predicate(s) with respect to indications for use or technology, this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences. Note that due to potential differences in manufacturing that may not be known to the submitter, no identified differences does not necessarily mean that no performance testing is needed.*		☐		☐
		Comments:				
D.	**Proposed Labeling (see also 21 CFR part 801)**					
	18.	Submission includes proposed labels, labeling (e.g., instructions for use,				

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
		package insert, operator's manual), and advertisements that describe the device, its intended use, and the directions for use				
		a.	Indications for use stated in labeling (21 CFR 801.61) and identical to IFU form and 510(k) Summary (if applicable)	☐		☐
		b.	Directions for use included (including relevant hazards, warnings, precautions, contraindications), including directions for layperson (see 21 CFR 801.5) unless submission states that device qualifies for exemption per 21 CFR 801 Subpart D.	☐		☐
		Comments:				
	19.	If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements] *Select "N/A" if not indicated for prescription use.*		☐	☐	☐
		Comments:				
	20.	General labeling provisions				
		a.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)	☐		☐
		b.	Labeling includes device common or usual name stated (21 CFR 801.61)	☐		☐
		Comments:				
	21.	If there is a device-specific guidance, special controls, or regulation, the provided labeling establishes that the submitter has followed the recommendations in the applicable guidance document, special controls, or regulation, or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "No" if the submission does not include a rationale for any*		☐	☐	☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.		**Yes**	**N/A**	**No**
		omitted information or any alternative approaches. Select "N/A" if there is no device-specific guidance.			
		Comments:			
	22.	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.*	☐	☐	☐
E.	**Performance Data – General**				
	Submission: (*one of the below must be checked*) ☐ does ☐ does not contain performance data. *If "does not" is selected, the performance data-related criteria are omitted from the checklist.*				
	Comments:				
	23.	Full test report is provided for each completed test that is not addressed within the scope of the Abbreviated 510(k) Criteria to explain how the data generated from the test supports a finding of substantial equivalence. (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, and conclusions.)	☐		☐
		Comments:			
	24.	Submission includes document to establish that the submitter has followed the recommendations for performance data outlined in the applicable device-specific guidance document or special controls, or otherwise met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no device-specific guidance document.*	☐	☐	☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
		Comments:				
	25.	If literature was used as performance data, submission includes reprints or a summary of each article, and a discussion as to how each article is applicable to support the substantial equivalence of the subject device to the predicate.		☐	☐	☐
		Comments:				
	26.	If an animal study was conducted, *Select "N/A" if no animal study was conducted.*			☐	
		a.	Submission includes a study protocol and final study report to explain how the data generated from the study supports a finding of substantial equivalence. (A final study report includes a contributing scientist report for each preclinical endpoint of evaluation within the protocol, such as performance/handling, in life, imaging, pathology, etc.)	☐		☐
		b.	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:				
F.	**Sterilization**					
	Submission states that the device and/or accessories are: (*one of the below must be checked*) ☐ sterile ☐ non-sterile but sterilized by the end user ☐ non-sterile when used					☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
	This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "non-sterile when used" is selected, the sterility-related criteria below are omitted from the checklist.* *If information regarding the sterility status of the device is not provided, select "No."*					
	Comments:					
	27.	Assessment of the need for sterilization information				
		a.	Identification of device, and/or accessories, and/or components that are provided sterile.	☐	☐	☐
		b.	Identification of device, and/or accessories, and/or components that are end user sterilized	☐	☐	☐
		c.	Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided.	☐	☐	☐
		Comments:				
	28.	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 parameters such as dry time for steam sterilization, radiation dose, etc.)	☐		☐
		b.	A description of method to validate the sterilization cycle (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided	☐		☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
		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.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package)	☐		☐
		e.	Sterility Assurance Level (SAL) stated	☐		☐
		f.	If device is blood-contacting, a permanent implant, or contacts cerebrospinal fluid, or device is labeled "non-pyrogenic," submission contains a description of the endotoxin method used to make a determination (e.g., LAL), endotoxin release specification (e.g., 20 EU/device), and a rationale for the specification *Select "N/A" if device is not blood-contacting, not a permanent implant, does not contact cerebrospinal fluid, and is not labeled "non-pyrogenic." Select "N/A" if a rationale for omission is provided.*	☐	☐	☐
		Comments:				
	29.	All sterility information provided as recommended in the following guidance documents or special controls, or information provided indicating the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach: *Either "a" or "b" must be answered "Yes" to be considered complete.*				
		a.	Device-specific guidance document or special controls *Select "N/A" if no device-specific guidance document or special controls.*	☐	☐	☐
		b.	Cross-cutting guidance document (for more information see	☐	☐	☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
			"Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile") *Select "N/A" if device-specific guidance or special controls followed instead.*			
		Comments:				
G.	**Shelf Life**					
	30.	If the device is provided sterile or the device is provided non-sterile and storage conditions (i.e., aging) could impact device safety or effectiveness, address the following: *Select "N/A" if the device is not provided sterile and the submitter states that the storage conditions could not affect device safety or effectiveness.*			☐	
		a.	Proposed shelf life/expiry date stated	☐		☐
		b.	Submission includes description of shelf life validation method(s) used to ensure device performance and sterility, as applicable, remain substantially equivalent to that of the predicate device throughout the stated shelf life.	☐		☐
		Comments:				
H.	**Biocompatibility**					
	Submission states that there: (*one of the below must be checked*) ☐ are ☐ are not direct or indirect (e.g., through fluid infusion) patient-contacting components. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.		**Yes**	**N/A**	**No**
	If "are not" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information regarding whether the device is patient-contacting is not provided, select "No."				
	Comments:				
	31.	Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	☐		☐
		Comments:			
	32.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)	☐		☐
		Comments:			
	33.	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)	☐		☐
I.	**Software**				
	Submission states that the device: (*one of the below must be checked*) ☐ does ☐ does not contain software.				☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.		**Yes**	**N/A**	**No**
	This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not" is selected, the software-related criterion is omitted from the checklist. If information regarding whether the device contains software is not provided, select "No."*				
	Comments:				
	34.	All appropriate categories of software verification and validation documentation provided based on stated level of concern, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submitter has provided documentation that it has otherwise met the applicable statutory or regulatory criteria through an alternative approach.	☐		☐
		Comments:			
J.	**EMC and Electrical Safety**				
	Submission states that the device: (*one of the below must be checked*) ☐ does ☐ does not require EMC and Electrical Safety evaluation. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not" is selected, the EMC-related and Electrical Safety-related criteria below are omitted from the checklist. If information regarding whether the device requires EMC and Electrical Safety evaluation is not provided, select "No."*				☐
	Comments:				
	35.	Submission includes evaluation of electrical safety per IEC 60601-1 or equivalent FDA-recognized standard and if applicable, the device-	☐		☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.		**Yes**	**N/A**	**No**
		specific standard OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and information indicating that these methods/standards otherwise meet applicable statutory and regulatory requirements.			
		Comments:			
	36.	Submission includes evaluation of electromagnetic compatibility per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and information indicating that these methods/standards otherwise meet applicable statutory and regulatory requirements.		☐		☐
		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 ☐ is not an in vitro diagnostic device (IVD). *If "is not" is selected, the performance data-related criteria are omitted from the checklist.*				
	Comments:				
	37.	Submission includes the following analytical studies, including associated protocols and line data:			

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
		a.	Precision/reproducibility (at least 3 sites generally necessary)	☐	☐	☐
		b.	Accuracy (includes linearity, assay cut-off, method comparison or comparison to clinical outcome, matrix comparison, reference range, and stability protocol and acceptance criteria)	☐	☐	☐
		c.	Sensitivity (detection limits (LoB, LoD, and LoQ))	☐	☐	☐
		Comments:				

Decision: Accept ___ Refuse to Accept ___

If Accept, notify applicant; if Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Team Leader Signature: _____ Date: _____

Supervisory Signature: _____ Date: _____

Contains Nonbinding Recommendations
Draft - Not for Implementation

Refuse to Accept 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.

510(k) Number: _____ **Date Received:** _____

Lead Reviewer Name: _____ **Branch:** _____ **Division:** _____ **Office:** _____

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).		
Comments:		

Does the submission meet all 4 criteria above?

☐ Yes, submission meets criteria for a Special 510(k). Continue with the remainder of this 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 along generally should not result in an RTA designation*		
	Yes	**No**
a. Submission contains Table of Contents		
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)		
c. 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…).*		
Comments:		

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
A.	**Administrative**					
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)		☐		☐
		Comments:				
	2.	510(k) Cover letter that identifies: at a minimum:		☐		☐
		a.	Device trade name or proprietary name	☐		☐
		b.	Device common name	☐		☐
		c.	Device class and panel	☐		☐
		Comments:				
	3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also and 801.109) *Submitter should use format appropriate for the reviewing*		☐		☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.		**Yes**	**N/A**	**No**
		Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request the correct format during substantive review.			
		Comments:			
	4.	Submission contains 510(k) Summary or 510(k) Statement *Either a) or b) must be answered "Yes" to be considered complete. Identify any missing element(s) as Comments.*	☐		☐
		a. Summary contains all elements per 21 CFR 807.92 *See also 510(k) Summary Checklist*	☐	☐	☐
		b. Statement contains all elements per 21 CFR 807.93	☐		☐
		Comments:			
	5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format*	☐		☐
		Comments:			
	6.	Submission contains Class III Summary and Certification *See recommended content* *Form should be signed by a responsible person of the firm, not a consultant. CDRH is not currently able to accept a digital signature.* *"N/A" only if submission is not a Class III 510(k).*	☐	☐	☐
		Comments:			
	7.	If submission relies upon a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (FDA Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	☐	☐	☐

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.		**Yes**	**N/A**	**No**
		There should be a completed form for each referenced national or international standard. *"N/A" only if submission does not reference any standards.*			
		Comments:			
	8.	If this is a bundled submission, the submission has been appropriately bundled [i.e., the correct user fee(s) have been paid for the devices/indications (Section 738 FD&C Act)] *See* Guidance for Industry and FDA Staff: Bundling Multiple Devices or Multiple Indications in a Single Submission. *"N/A" if not a bundled submission*	☐	☐	☐
		Comments:			
	9.	The submission identifies related submissions for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions.	☐		☐
		a. If there are related submissions, within current submission, the sponsor has identified where in the current submission any issues related to substantial equivalence outlined in prior communications are addressed.	☐		☐
		Comments:			
B.	**Device Description**				
	10.	If there is a device-specific guidance document or special controls applicable to this submission, documentation has been provided to establish that the submitter has followed the recommendations in the applicable device-specific guidance document or special controls regarding the device description or otherwise met the applicable	☐	☐	☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
		statutory or regulatory criteria through an alternative approach. *Select "No" if the submission does not include a rationale for any omitted information or any alternative approaches.* *Select "N/A" if there is no device-specific guidance document*				
		Comments:				
	11.	All descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
		a.	A description of the principle of operation and mechanism of action for achieving the intended therapeutic/diagnostic effect.	☐		☐
		b.	A description of all 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 model for which clearance is requested. *Select "N/A" if there is only one model.*	☐	☐	☐
		Comments:				
	12.	A description of all device modification(s) including rationale for each modification.		☐		☐
		Comments:				
	13.	Identification of history of changes made to device since the previous 510(k) clearance		☐		☐
		Comments:				

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
	14.	Where applicable, submission contains engineering drawing(s), schematics, illustrations and/or figures of the device that are clear and legible, and include dimensions		☐	☐	☐
		a.	If engineering drawings, schematics, illustrations and/or figures are provided, one is provided for each model to be marketed	☐	☐	☐
		Comments:				
	15.	If 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.*			☐	
		a.	A description (as detailed in item #12.a. and b. and 14 above) is provided for each component or accessory.	☐		☐
		b.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. *Select "N/A" if the submission states that the component(s)/ accessory(ies) do not have a prior 510(k) clearance.*	☐	☐	☐
		Comments:				
C.	**Substantial Equivalence Discussion**					
	16.	Submitter has identified a predicate(s) device		☐		☐
		a.	Predicate's 510(k) number, trade name, and model number (if applicable) provided	☐		☐
		b.	The identified predicate(s) is consistent throughout the submission (i.e., 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)	☐		☐

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.			**Yes**	**N/A**	**No**
		Comments:				
	17.	Submission includes a comparison of the following for the predicate(s) and subject device				
		a.	Indications for use	☐		☐
		b.	Technology, including features, materials, and principles of operation	☐		☐
		Comments:				
	18.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., do not constitute a new intended use, affect safety or effectiveness, or raise different questions of safety and effectiveness) (see section 513(i)(l)(A) of the FD&C Act) *If there is no difference between the subject and predicate(s with respect to the indications or technology), this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences.*		☐		☐
		Comments:				
D.	**Design Control Activities**					
	19.	Design Control Activities Summary includes all of the following:				
		a.	Identification of Risk Analysis methods(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.	☐		☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed								
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.								
	• Any "No" answer will result in a "Refuse to Accept" decision. • 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.						**Yes**	**N/A**	**No**
		c.	Declaration of conformity with design controls, including: *All 3 must be present to answer "Yes"*				☐		☐
			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 part 801)**								
	20.	Submission includes proposed labels, labeling (e.g., instructions for use, package insert, operator's manual) and advertisements that describe the device, its intended use, and the directions for use					☐		☐
		a.	All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified.				☐		☐
	Comments:								
	21.	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 applicant; if Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Team Leader Signature: _____ Date: _____

Supervisory Signature: _____ Date: _____