

Contains Nonbinding Recommendations

Acceptance Checklist for Traditional 510(k)s

(should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

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

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

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

| Preliminary Questions | | |
|---|-----|----|
| Answers in the shaded blocks indicate consultation with Center advisor is needed. | Yes | No |
| <p>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)?</p> <p>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. <i>Provide a summary of the Jurisdictional Officer's/Liaison's determination.</i> If the product does not appear to be a device or such a combination product, mark "No."</p> | | |
| Comments: | | |
| <p>2. Is the application with the appropriate Center?</p> <p>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. <i>Provide a summary of the Jurisdictional Officer's/Liaison's determination.</i> If application should not be reviewed by your Center mark "No."</p> | | |
| Comments: | | |
| <p>3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following:</p> | | |

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| | | |
|--|--|--|
| <p>a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?</p> <p>b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?</p> <p>If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. <i>Provide summary of Jurisdictional Officer's/Liaison's determination.</i></p> <p>If the answer to either question above is no, mark "No." If there was no RFD, skip this question.</p> | | |
| <p>Comments:</p> | | |
| <p>4. Is this device type eligible for a 510(k) submission?</p> <p>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."</p> | | |
| <p>Comments:</p> | | |
| <p>5. Is there a pending PMA for the same device with the same indications for use?</p> <p>If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.</p> | | |
| <p>Comments:</p> | | |
| <p>6. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)?</p> <p>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.</p> | | |

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.

If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.

If the answer to 4 is "No", the lead reviewer should consult division management and other Center resources to determine the appropriate action.

If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.

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If the answer to 6 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.

| <u>Organizational Elements</u> | | |
|---|--------------------------|--------------------------|
| <i>Failure to include these items alone generally should not result in an RTA designation</i> | | |
| | Yes | No |
| a. Submission contains Table of Contents | <input type="checkbox"/> | <input type="checkbox"/> |
| b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.) | <input type="checkbox"/> | <input type="checkbox"/> |
| c. All pages of the submission are numbered <i>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...).</i> | <input type="checkbox"/> | <input type="checkbox"/> |
| d. Type of 510(k) is identified– traditional, abbreviated, or special <i>If type of 510(k) is not designated, review as a traditional</i> | <input type="checkbox"/> | <input type="checkbox"/> |
| Comments: | | |

| <u>Elements of a Complete Submission (RTA Items)</u> | | | | |
|---|---|--------------------------|------------|--------------------------|
| <u>(21 CFR 807.87 unless otherwise indicated)</u> | | | | |
| 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. | | | | |
| | | Yes | N/A | No |
| | <ul style="list-style-type: none"> 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. | | | |
| A. | Administrative | | | |
| | 1. All content used to support the submission is written in English (including translations of test reports, literature articles, etc.) | <input type="checkbox"/> | | <input type="checkbox"/> |
| | Comments: | | | |
| | 2. Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter): | <input type="checkbox"/> | | <input type="checkbox"/> |
| | a. Device trade name or proprietary name | <input type="checkbox"/> | | <input type="checkbox"/> |
| | b. Device common name | <input type="checkbox"/> | | <input type="checkbox"/> |

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| <u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u> | | | | | | | |
|---|---|--|--------------------------|--------------------------|--------------------------|------------|-----------|
| 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. | | | | | | | |
| | <ul style="list-style-type: none"> 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. | Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion | <input type="checkbox"/> | | <input type="checkbox"/> | | |
| | Comments: | | | | | | |
| | 3. | Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109) <i>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.</i> | <input type="checkbox"/> | | <input type="checkbox"/> | | |
| | Comments: | | | | | | |
| | 4. | Submission contains 510(k) Summary or 510(k) Statement <i>Either a) or b) must be answered “Yes” to be considered complete. Identify any missing element(s) in Comments.</i> | <input type="checkbox"/> | | <input type="checkbox"/> | | |
| | a. | Summary contains all elements per 21 CFR 807.92 <i>See also 510(k) Summary Checklist</i> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | |
| | b. | Statement contains all elements per 21 CFR 807.93 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | |
| | Comments: | | | | | | |
| | 5. | Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) <i>See recommended format. Select “Yes” if statement is present and includes the text in the recommended format, and is signed by a responsible person of the firm (not consultant).</i> | <input type="checkbox"/> | | <input type="checkbox"/> | | |
| | Comments: | | | | | | |

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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.

| | | <ul style="list-style-type: none"> 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 |
|----|--|---|--------------------------|--------------------------|--------------------------|
| 6. | Submission contains Class III Summary and Certification <i>See recommended content. Form should be signed by a responsible person of the firm, not a consultant. Select “N/A” only if submission is not a Class III 510(k).</i> | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | Comments: | | | | |
| 7. | Submission contains clinical data <i>Select “N/A” if the submission does not contain clinical data. If “N/A” is selected, parts a and b below are omitted from the checklist.</i> | | <input type="checkbox"/> | <input type="checkbox"/> | |
| a. | Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each covered clinical study included in the submission. <i>Select “N/A” if the submitted clinical data is not a “covered clinical study” as defined in the Guidance for Industry- Financial Disclosures by Clinical Investigators</i> | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b. | Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. <i>Select “N/A” if the submitted clinical data is not an “applicable device clinical trial” as defined in Title VIII of FDAAA, Sec. 801(j)</i> | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | Comments: | | | | |
| 8. | If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains complete Standards Data Report for 510(k)s (FDA Form 3654) <i>There should be a completed form for each referenced national or international standard. Select “N/A” only if submission does not reference any standards.</i> | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.

| | | <ul style="list-style-type: none"> 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: | | | |
| | 9. | <p>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 for the subject device.</p> <p><i>This information may be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions). Alternatively, a list of submission numbers may be found in Section F (prior related submissions section) of the CDRH Coversheet form (Form 3514) to address this criterion. Please be advised that if this section of the form is left blank, it should not be considered a statement that there were no prior submissions.</i></p> | <input type="checkbox"/> | | <input type="checkbox"/> |
| | a. | <p>If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed.</p> <p><i>To address this criterion, the submission may include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that the adequacy of how the feedback was addressed should be assessed during the substantive review. 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” (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm). Once finalized, this guidance will represent the</i></p> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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| <u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u> | | | | | | | |
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| 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. | | | | | | | |
| | <ul style="list-style-type: none"> 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 |
| | | | Agency’s current thinking on this topic. <i>Select “N/A” if the submitter states there were no prior submissions in criterion above.</i> | | | | |
| | | Comments: | | | | | |
| B. | Device Description | | | | | | |
| | 10. | a. | If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement. <i>Select “N/A” if there are no applicable requirements in a device-specific regulation. Select “No” if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.</i> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| | | b. | If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. <i>Select “N/A” if there is no applicable device-specific guidance. Select “No” if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.</i> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| | | Comments: | | | | | |

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| 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. | | | | | |
| | <ul style="list-style-type: none"> 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 | |
| | 11. | 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 effect. | <input type="checkbox"/> | | <input type="checkbox"/> |
| | b. | A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient. | <input type="checkbox"/> | | <input type="checkbox"/> |
| | c. | A list and description of each device for which clearance is requested. <i>Select “N/A” if there is only one device or model. “Device” may refer to models, part numbers, or various sizes, etc.</i> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | Comments: | | | |
| | 12. | Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions. <i>In lieu of drawings, schematics, etc. of each device to be marketed, “representative” drawings, etc. may be provided, where “representative” is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.</i> <i>Select “N/A” if the submitter provided a rationale for why the submission does not contain engineering drawings, schematics, etc. (e.g., device is a reagent and figures are not pertinent to describe the device).</i> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | Comments: | | | |

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| 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. | | | | | |
| | <ul style="list-style-type: none"> 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 | |
| | 13. | If device is intended to be marketed with multiple components, accessories, and/or as part of a system, <i>Select “N/A” if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.</i> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | a. | Submission includes a list of all components and accessories to be marketed with the subject device. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | b. | Submission includes a description (as detailed in item 11.a. and b. and 12 above) of each component or accessory. <i>Select “N/A” if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.</i> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | c. | A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. <i>Select “N/A” if the submission states that the component(s)/accessory(ies) does not have a prior 510(k) clearance or the component(s)/accessory(ies) is 510(k) exempt.</i> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | Comments: | | | |
| C. | Substantial Equivalence Discussion | | | | |
| | 14. | Submitter has identified a predicate(s) device | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | a. | Predicate’s 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. <i>Information regarding documenting preamendment status is available online</i> (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidan) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.

| <ul style="list-style-type: none"> 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 |
|---|--|--------------------------|--------------------------|--------------------------|
| | ce/ComplianceActivities/ucm072746.htm). | | | |
| | 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. | <input type="checkbox"/> | | <input type="checkbox"/> |
| | Comments: | | | |
| 15. | Submission includes a comparison of the following for the predicate(s) and subject device | | | |
| | a. Indications for use | <input type="checkbox"/> | | <input type="checkbox"/> |
| | b. Technology, including features, materials, and principles of operation | <input type="checkbox"/> | | <input type="checkbox"/> |
| | Comments: | | | |
| 16. | Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)) <i>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 the adequacy of the analysis should be assessed during the substantive review; only the presence of such an analysis is required for acceptance. In addition, note that due to potential differences in</i> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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| Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed. | | | | | |
| | | | Yes | N/A | No |
| | <ul style="list-style-type: none"> 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. | | | | |
| | <i>manufacturing that may not be known to the submitter, the fact that no differences are identified does not necessarily mean that no performance testing is needed.</i> | | | | |
| | Comments: | | | | |
| D. | Proposed Labeling (see also 21 CFR part 801) <i>If in vitro diagnostic (IVD) device, criteria 17, 18, and 19 may be omitted. These criteria will be omitted from the checklist if “N/A” is selected. IVD labeling is addressed in section 21 below.</i> | | | <input type="checkbox"/> | |
| | 17. Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator’s manual) that include a description of the device, its intended use, and the directions for use | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | a. Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided) | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | b. Submission includes directions for use that <ul style="list-style-type: none"> - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) AND - Includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | Comments: | | | | |
| | 18. 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] <i>Select “N/A” if not indicated for prescription use.</i> | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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| 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. | | | | | | |
| | | <ul style="list-style-type: none"> 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: | | | | |
| | 19. | General labeling provisions | | | | |
| | a. | Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| | b. | Labeling includes device common or usual name (21 CFR 801.61) <i>Select “N/A” if device is for prescription use only.</i> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| | | Comments: | | | | |
| | 20. | a. | If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement. <i>Select “N/A” if there are no applicable requirements in a device-specific regulation. Select “No” if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.</i> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | b. | If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. <i>Select “N/A” if there is no applicable device-specific guidance. Select “No” if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.</i> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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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.

| | | <ul style="list-style-type: none"> 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. | <p>If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.</p> <p><i>Select “N/A” if there is no applicable special controls document. Select “No” if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.</i></p> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | Comments: | | | | |
| | 21. | <p>If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.</p> <p><i>Select “N/A” if not an in vitro diagnostic device.</i></p> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| E. | <p>Sterilization</p> <p><i>If in vitro diagnostic (IVD) device and sterilization is not applicable, select “N/A.” The criteria in this section will be omitted from the checklist if “N/A” is selected.</i></p> | | | <input type="checkbox"/> | |
| | <p>Submission states that the device and/or accessories are: <i>(one of the below must be checked)</i></p> <p><input type="checkbox"/> provided sterile</p> <p><input type="checkbox"/> provided non-sterile but sterilized by the end user</p> <p><input type="checkbox"/> non-sterile when used</p> <p>This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.</p> <p><i>If “non-sterile when used” is selected, the sterility-related criteria below are omitted from</i></p> | | | | <input type="checkbox"/> |

Contains Nonbinding Recommendations

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.

| | | <ul style="list-style-type: none"> 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 |
|-----|---|---|--------------------------|--------------------------|--------------------------|
| | | <i>the checklist.</i> <i>If information regarding the sterility status of the device is not provided, select “No.”</i> | | | |
| | | Comments: | | | |
| 22. | Assessment of the need for sterilization information | | | | |
| | a. | Identification of device, and/or accessories, and/or components that are provided sterile. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | b. | Identification of device, and/or accessories, and/or components that are end user sterilized | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | c. | Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | Comments: | | | |
| 23. | If the device, and/or accessory, and/or a component is provided sterile: <i>Select “N/A” if no part of the device, accessories, or components is provided sterile, otherwise complete a-e below.</i> | | | <input type="checkbox"/> | |
| | a. | Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.) | <input type="checkbox"/> | | <input type="checkbox"/> |
| | b. | A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. <i>Note, the sterilization validation report is not required.</i> | <input type="checkbox"/> | | <input type="checkbox"/> |
| | c. | For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.

| | | <ul style="list-style-type: none"> 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 |
|--|-----------|---|--------------------------|--------------------------|--------------------------|
| | | levels of sterilant residuals remaining on the device and sterilant residual limits. <i>Select “N/A” if not sterilized using chemical sterilants.</i> | | | |
| | d. | Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.) | <input type="checkbox"/> | | <input type="checkbox"/> |
| | e. | Sterility Assurance Level (SAL) stated | <input type="checkbox"/> | | <input type="checkbox"/> |
| | Comments: | | | | |
| | 24. | If the device, and/or accessory, and/or a component is end user sterilized: <i>Select “N/A” if no part of the device, accessories, or components are end user sterilized, otherwise complete a-d below.</i> | | <input type="checkbox"/> | |
| | a. | Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.) | <input type="checkbox"/> | | <input type="checkbox"/> |
| | b. | A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. <i>Note, the sterilization validation is not required.</i> | <input type="checkbox"/> | | <input type="checkbox"/> |
| | c. | Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.) | <input type="checkbox"/> | | <input type="checkbox"/> |
| | d. | Submission includes sterilization instructions for end user | <input type="checkbox"/> | | <input type="checkbox"/> |
| | Comments: | | | | |
| | 25. | a. If there are requirements regarding sterility, such as special | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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|---|--|----|--|--------------------------|--------------------------|--------------------------|----|
| 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. | | | | | | | |
| <ul style="list-style-type: none"> • 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 |
| | | | <p>controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement. <i>Select “N/A” if there are no applicable requirements in a device-specific regulation. Select “No” if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.</i></p> | | | | |
| | | b. | <p>If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. <i>Select “N/A” if there is no applicable device-specific guidance. Select “No” if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.</i></p> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| | | c. | <p>If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. <i>Select “N/A” if there is no applicable special controls document. Select “No” if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a</i></p> | | | | |

Contains Nonbinding Recommendations

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|---|---|---|--|------------|--------------------------|--------------------------|--------------------------|
| 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. | | | | | | | |
| | | | | | | | |
| | <ul style="list-style-type: none"> 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 | |
| | | | <i>special controls document have been addressed should be assessed during the substantive review.</i> | | | | |
| | | Comments: | | | | | |
| F. | Shelf Life | | | | | | |
| | 26. | Proposed shelf life/ expiration date stated <i>Select “N/A” if the device is not provided sterile and the submitter states that storage conditions could not affect device safety or effectiveness.</i> | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | Comments: | | | | | |
| | 27. | For sterile device, submission includes summary of methods used to establish that device sterility will remain substantially equivalent to that of the predicate through the proposed shelf life, or a rationale for why testing to establish shelf life is not applicable. <i>Select “N/A” if the device is not provided sterile.</i> | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | Comments: | | | | | |
| | 28. | Submission includes summary of methods used to establish that device performance is not adversely affected by aging and therefore device performance will remain substantially equivalent to that of the predicate, or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness. | | | <input type="checkbox"/> | | <input type="checkbox"/> |
| | | Comments: | | | | | |
| G. | Biocompatibility | | | | | <input type="checkbox"/> | |
| | <i>If in vitro diagnostic (IVD) device, select “N/A.” The criteria in this section will be omitted from the checklist if “N/A” is selected.</i> | | | | | | |
| | Submission states that there: <i>(one of the below must be checked)</i> <input type="checkbox"/> are | | | | | <input type="checkbox"/> | |

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| <u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u> | | | | |
|---|--|--------------------------|-----|--------------------------|
| 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. | | | | |
| | <ul style="list-style-type: none"> 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 |
| | <input type="checkbox"/> 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. <i>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.”</i> | | | |
| | Comments: | | | |
| | 29. Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present | <input type="checkbox"/> | | <input type="checkbox"/> |
| | Comments: | | | |
| | 30. Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration) | <input type="checkbox"/> | | <input type="checkbox"/> |
| | Comments: | | | |
| | 31. 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). | <input type="checkbox"/> | | <input type="checkbox"/> |
| | Comments: | | | |
| H. | Software | | | |

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|---|--|--------------------------|-----|--------------------------|
| 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. | | | | |
| | <ul style="list-style-type: none"> 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 states that the device: <i>(one of the below must be checked)</i> <input type="checkbox"/> does <input type="checkbox"/> does not contain software/firmware. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>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.”</i> | | | <input type="checkbox"/> |
| | Comments: | | | |
| 32. | Submission includes a statement of software level of concern and rationale for the software level of concern | <input type="checkbox"/> | | <input type="checkbox"/> |
| | Comments: | | | |
| 33. | All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices , or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale). | <input type="checkbox"/> | | <input type="checkbox"/> |
| | Comments: | | | |
| I. | EMC and Electrical Safety | | | |
| | Submission states that the device: <i>(one of the below must be checked)</i> <input type="checkbox"/> does <input type="checkbox"/> does not require EMC and Electrical Safety evaluation. | | | <input type="checkbox"/> |

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(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.

| | <ul style="list-style-type: none"> • 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 |
|-----|---|--------------------------|-----|--------------------------|
| | <p>This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>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.”</i></p> | | | |
| | Comments: | | | |
| 34. | <p>Submission includes evaluation of electrical safety (e.g., 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 submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).</p> | <input type="checkbox"/> | | <input type="checkbox"/> |
| | Comments: | | | |
| 35. | <p>Submission includes evaluation of electromagnetic compatibility (e.g., 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 submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).</p> | <input type="checkbox"/> | | <input type="checkbox"/> |
| | Comments: | | | |

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|---|---|--------------------------|--------------------------|--------------------------|
| 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. | | | | |
| | <ul style="list-style-type: none"> 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. | <p>Performance Data – General</p> <p><i>If in vitro diagnostic (IVD) device, select “N/A.” The criteria in this section will be omitted from the checklist if “N/A” is selected. Performance data criteria relating to IVD devices will be addressed in Section K.</i></p> | | <input type="checkbox"/> | |
| | Comments: | | | |
| | <p>36. Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.</p> <p><i>Full test reports provided for all completed tests/evaluations (e.g., bench evaluations, comparative performance tests, etc.). Select “N/A” if the submission does not include performance data.</i></p> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | Comments: | | | |
| | <p>37. a. If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.</p> <p><i>Select “N/A” if there are no applicable requirements in a device-specific regulation. Select “No” if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.</i></p> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | <p>b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative</p> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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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.

| | | <ul style="list-style-type: none"> 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 |
|--|-----------|--|--------------------------|--------------------------|--------------------------|
| | | <p>approach. <i>Select “N/A” if there is no applicable device-specific guidance. Select “No” if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.</i></p> | | | |
| | c. | <p>If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. <i>Select “N/A” if there is no applicable special controls document. Select “No” if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.</i></p> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | Comments: | | | | |
| | 38. | <p>If literature is referenced in the submission, submission includes: <i>Select “N/A” if the submission does not reference literature. Note that the applicability of the referenced article to support a substantial equivalence finding should be assessed during the substantive review; only the presence of a discussion is required to support acceptance.</i></p> | | <input type="checkbox"/> | |
| | a. | Legible reprints or a summary of each article | <input type="checkbox"/> | | <input type="checkbox"/> |
| | b. | Discussion of how each article is applicable to support the | <input type="checkbox"/> | | <input type="checkbox"/> |

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|---|--|--|--|--------------------------|-----|--------------------------|--|
| 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. | | | | | | | |
| | | | | Yes | N/A | No | |
| | | | substantial equivalence of the subject device to the predicate. | | | | |
| | | Comments: | | | | | |
| | 39. | For each completed nonclinical (i.e., animal) study conducted, <i>Select “N/A” if no animal study was conducted. Note that this section does not address biocompatibility evaluations, which are assessed in Section G of the checklist,</i> | | | | <input type="checkbox"/> | |
| | | a. | Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120 | <input type="checkbox"/> | | <input type="checkbox"/> | |
| | | b. | Submission includes final study report which includes all elements outlined in 21 CFR 58.185 | <input type="checkbox"/> | | <input type="checkbox"/> | |
| | | c. | Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination. | <input type="checkbox"/> | | <input type="checkbox"/> | |
| | | Comments: | | | | | |
| K. | Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12)) | | | | | | |
| | Submission indicates that device: <i>(one of the below must be checked)</i> <input type="checkbox"/> is <input type="checkbox"/> is not an in vitro diagnostic device (IVD). <i>If “is not” is selected, the performance data-related criteria below are omitted from the checklist.</i> | | | | | | |
| | Comments: | | | | | | |

Contains Nonbinding Recommendations

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|---|-----|--|--------------------------|--------------------------|--------------------------|
| 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. | | | | | |
| | | <ul style="list-style-type: none"> 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 |
| | 40. | Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data: | | | |
| | | a. Precision/reproducibility | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | b. Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | c. Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type). | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | d. Analytical specificity | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | Comments: | | | |
| | 41. | a. If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement. <i>Select “N/A” if there are no applicable requirements in a device-specific regulation. Select “No” if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.</i> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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| <u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u> | | | | | | | |
|---|--|-----------|---|--------------------------|--------------------------|--------------------------|--|
| 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. | | | | | | | |
| | | | <ul style="list-style-type: none"> 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 | |
| | | | applicable statutory or regulatory criteria through an alternative approach. <i>Select “N/A” if there is no applicable device-specific guidance. Select “No” if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.</i> | | | | |
| | | c. | If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. <i>Select “N/A” if there is no applicable special controls document. Select “No” if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.</i> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| | | Comments: | | | | | |

Contains Nonbinding Recommendations

Decision: Accept ____ Refuse to Accept ____

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

Reviewer Signature: _____ **Date:** _____

Supervisory Signature: _____ **Date:** _____