Checklist for Traditional 510(k)s

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

Preliminary Questions			
Answers in the shaded blocks indicate consultation with an identified Center advisor is needed. (Boxes checked in this section represent FDA's preliminary assessment of these questions at the time of administrative review.)	**Yes**	**No**	**N/A**
1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product (per 21 CFR 3.2(e)), or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action, and inform management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below*.	☐	☐	

If the product does not appear to be a device or such a combination product, mark "No."			
Comments:			
2. Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If submission should not be reviewed by your Center mark "No."	☐	☐	
Comments:			
3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **(a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **(b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."	☐	☐	☐
Comments:			
4. Is the submission for a combination product that contains as a constituent part a drug that has the same active moiety as an approved drug with exclusivity as described in section 503(g)(5)(C)(ii)-(v) of the FD&C Act? If "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide the summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.*	☐	☐	☐
Comments:			

5. Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., class III type and PMA required, or class I or II type and 510(k)-exempt), consult with the appropriate CDRH or CBER staff during the acceptance review, provide a summary of the discussion with them, and indicate their recommendation/action in the comment section below. If 510(k) is not the appropriate regulatory submission, mark "No."	☐	☐	
Comments:			
6. Is there a pending PMA for the same device with the same indications for use? If "Yes," consult your management and CDRH Office of Product Evaluation and Quality/Office of Regulatory Programs/Division of Regulatory Programs 1 (Submission Support) (OPEQ/ORP/DRP1) or appropriate CBER staff to determine the appropriate action.	☐	☐	
Comments:			
7. 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 Product Evaluation and Quality/Office of Clinical Evidence and Analysis/Division of Clinical Science and Quality (OPEQ/OCEA/DCEA1) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action, provide a summary of the discussion with them, and indicate their recommendation/action. If no clinical studies have been submitted, mark "N/A." Check on the AIP list at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/application-integrity-policy/application-integrity-policy-list.	☐	☐	☐
Comments:			

- **If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.**
- **If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.**
- **If the answer to 4 is "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer, provide a summary of the discussion with them, and indicate their recommendation/action.**
- **If the answer to 5 is "No", the lead reviewer should consult division management and other Center resources to determine the appropriate action. Note that, for a device which is clearly ineligible for a 510(k) submission (such as a device type which is class III requiring PMA or**

class I/II and 510(k) exempt), this may be considered a basis for a refusal to accept the submission. A 510(k) submitted for a class I/II, 510(k)-exempt device that trips the limitations of the exemption would not be refused on this basis.

- **If the answer to 6 is "Yes," then stop review of the 510(k), contact CDRH/OPEQ/ORP/DRP1, or appropriate CBER staff.**
- **If the answer to 7 is "Yes," then contact CDRH/OPEQ/OCEA/DCEA1 or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DCEA1 or BMB Staff, and indicate their recommendation/action.**

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

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

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
A.	**Administrative**						
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.).		☐	☐		
		Comments:					
	2.	Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download)):					
		a.	Device trade/proprietary name	☐	☐		
		b.	Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	☐	☐		
		Comments:					
	3.	Submission contains an Indications for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's final rule, "Use of Symbols in Labeling" (81 FR 38911), available at https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling). *See recommended format (https://www.fda.gov/media/86323/download).*		☐	☐		
		Comments:					
	4.	Submission contains a 510(k) Summary or 510(k) Statement. *Refer to 21 CFR 807.92 and 21 CFR 807.93 for contents of 510(k) Summary and Statement, respectively. Adequacy of the content will be assessed during substantive review.*		☐	☐		
		Comments:					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	5.	Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(*l*). *See recommended format (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement).*		☐	☐		
		Comments:					
	6.	Submission is a class III 510(k) Device. *Select "N/A" only if submission is not a class III 510(k).*		☐		☐	
		a.	Contains class III Summary and Certification per 21 CFR 807.87(k). *See recommended content (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-class-iii-certification-and-summary). Select "N/A" only if submission is not a class III 510(k).*	☐	☐	☐	
		Comments:					
	7.	Submission contains clinical data. *Select "N/A" if the submission does not contain clinical data. If "N/A" is selected, parts a, b, and c below are omitted from the checklist.*		☐		☐	
		a.	Submission includes completed Financial Certification (FDA Form 3454, available at https://www.fda.gov/media/70465/download) or Disclosure (FDA Form 3455, available at https://www.fda.gov/media/69872/download) information for each covered clinical study included in the submission. *Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the guidance entitled "Financial Disclosures by Clinical Investigators," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/financial-disclosure-clinical-investigators.*	☐	☐	☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		b.	Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (see FDA Form 3674 which can be obtained at https://www.fda.gov/about-fda/reports-manuals-forms/forms) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. *Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j).*	☐	☐	☐	
		c.	Statements of Compliance for Clinical Investigations *Select "N/A" if the submission does not contain any clinical data from investigations (as defined in 21 CFR 812.3(h)) to demonstrate substantial equivalence.* *For multicenter clinical investigations involving both United States (US) and outside United States (OUS) sites, part (i) should be addressed for the US sites and part (ii) should be addressed for the OUS sites. 21 CFR 812.28 applies to all OUS clinical investigations that enroll the first subject on or after February 21, 2019.* *Please refer to the guidance document entitled "Acceptance of Clinical Data to Support Medical Device Applications and Submissions - Frequently Asked Questions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-clinical-data-support-medical-device-applications-and-submissions-frequently-asked for more information.*	☐		☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**					**Yes**	**No**	**N/A**	***Page #**
			i.	For each clinical investigation conducted in the US, the submission includes a statement that the investigation was conducted in compliance with 21 CFR parts 50, 56, and 812 (or, with respect to part 56, that it was not subject to the regulations under 21 CFR 56.104 or 56.105). **OR** The submission includes a brief statement of the reason for noncompliance with 21 CFR parts 50, 56, and/or 812. *Select "N/A" if the clinical investigations were conducted solely OUS.*	☐	☐	☐	
			ii.	For each clinical investigation conducted OUS, the submission includes a statement that the clinical investigations were conducted in accordance with good clinical practice (GCP) as described in 21 CFR 812.28(a)(1). **OR** The submission includes a waiver request in accordance with 21 CFR 812.28(c). **OR** The submission includes a brief statement of the reason for not conducting the investigation in accordance with GCP and a description of steps taken to ensure that the data and results are credible and accurate and that the rights, safety, and well-being of subjects have been adequately protected. *Select "N/A" if the clinical investigations were conducted solely inside the US.*	☐	☐	☐	
			Comments:					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	8.	The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Q-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device. *Prior submissions (or no prior submissions) for this device should be included in Section F (prior related submissions) of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download). This information may also be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions).*		☐	☐		
		a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed. *To address this criterion, it is recommended that the submission include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that adequacy of how the feedback was addressed will be assessed during the substantive review.* *Select "N/A" if the submitter states there were no prior submissions.*	☐	☐	☐	
			Comments:				
	9.	The submission utilizes voluntary consensus standard(s) (See section 514(c) of the FD&C Act). *This includes both FDA-recognized and non-recognized consensus standards. Select "N/A" if the submission does not utilize voluntary consensus standards.*		☐		☐	
		a.	The submission cites FDA-recognized voluntary consensus standard(s).	☐		☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**					**Yes**	**No**	**N/A**	***Page #**
			i.	The submission includes a Declaration of Conformity (DOC) as outlined in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. **OR** If citing general use of a standard as noted in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," the basis of such use is included along with the underlying information or data that supports how the standard was used.	☐	☐		
		b.	The submission cites non-FDA-recognized voluntary consensus standard(s).		☐		☐	
			i.	The basis of use is included along with the underlying information or data that supports how the standard was used.	☐	☐		
		Comments:						
	Combination Product Provisions – Per 503(g) of the FD&C Act. Select "N/A" if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.						☐	
	10.	Submission identifies the product as a combination product.			☐	☐		
	11.	The combination product contains as a constituent part an approved drug as defined in section 503(g)(5)(B) of the FD&C Act. Select "N/A" if the combination product does not contain as a constituent part an approved drug. Please also select "N/A" if a right of reference or use for the drug constituent part(s) is included with the submission. If "N/A" is selected, part a below is omitted from the checklist.			☐		☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		a.	The submission includes appropriate patent statement or certification and a statement that the submitter will give notice, as applicable. See section 503(g)(5)(A)&(C) of the FD&C Act.	☐	☐		
			Comments:				
B.	**Device Description**						
	12.	The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*		☐		☐	
		a.	The submission addresses device description recommendations outlined in the device-specific guidance. **<u>OR</u>** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	

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

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		d.	Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device). *In lieu of engineering drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.*	☐	☐		
			Comments:				
	15.	Device is intended to be marketed with accessories and/or as part of a system. *Select "N/A" if the device is not intended to be marketed with accessories and/or as part of a system. If "N/A" is selected, parts a-c below are omitted from the checklist.*		☐		☐	
		a.	Submission includes a list of all accessories to be marketed with the subject device.	☐	☐		
		b.	Submission includes a description (as detailed in item 14a., 14b., and 14d. above) of each accessory. *Select "N/A" if the accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.*	☐	☐	☐	
		c.	A 510(k) number is provided for each accessory that received a prior 510(k) clearance. **AND** A statement is provided that identifies accessories that have not received prior 510(k) clearance.	☐	☐		
			Comments:				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
C.	**Substantial Equivalence Discussion**						
	16.	Submitter has identified a predicate device(s), including the following information:					
		a.	Predicate device identifier provided (e.g., 510(k) number, De Novo number, reclassified PMA number, classification regulation reference, if exempt (e.g., 21 CFR 872.3710), or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status).*	☐	☐		
		b.	The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	☐	☐		
			Comments:				
	17.	Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)]. *See the FDA guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k for more information on comparing intended use and technological characteristics.*				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		a.	Indications for use *If there are no differences between the subject device and the predicate(s) with respect to indications and intended use, this should be explicitly stated.*	☐	☐		
		b.	Technology, including technical specifications, features, materials, and principles of operation *Examples of technological characteristics include, but are not limited to design, features, materials, energy source, and principle of operation.* *FDA recommends a tabular format for comparing technological characteristics. Any characteristic that is the same as the predicate(s) should be explicitly stated. Differences in technological characteristics should be identified and a rationale provided why they do not raise different questions of safety and effectiveness.*	☐	☐		
			Comments:				
D.	**Proposed Labeling (see also 21 CFR parts 801 and 809 as applicable)**						
	18.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).		☐	☐		
		a.	Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	☐	☐		
		b.	Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
			Comments:				
	19.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).		☐	☐		
		Comments:					
	20.	Labeling includes the prescription statement (see 21 CFR 801.109(b)(1)) or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's final rule, "Use of Symbols in Labeling" (81 FR 38911), available at https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling). *Select "N/A" if not indicated for prescription use.*		☐	☐	☐	
		Comments:					
	21.	The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding labeling that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*		☐		☐	
		a.	The submission addresses labeling recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	

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

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

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

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		f.	For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]). *Select "N/A" if not labeled "non-pyrogenic."*	☐	☐	☐	
			Comments:				
	25.	If the device and/or accessory, if applicable, is reusable or end user sterilized or disinfected: *Select "N/A" if no part of the device or accessories are reusable or end user sterilized or disinfected, otherwise complete a-d below.*				☐	
		a.	Cleaning method is provided in labeling for each device and/or accessory, if applicable. *Select "N/A" if not reusable and does not need cleaning prior to disinfection or sterilization.*	☐	☐	☐	
		b.	Disinfection method is provided in labeling for each device and/or accessory, if applicable. *Select "N/A" if not disinfected (i.e., undergoes terminal sterilization) prior to use.*	☐	☐	☐	
		c.	Sterilization method is provided in labeling for each device and/or accessory, if applicable. *Select "N/A" if not sterilized (i.e., undergoes disinfection) prior to use.*	☐	☐	☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**					**Yes**	**No**	**N/A**	***Page #**
		d.	Device types in this submission are listed in the Federal Register (FR) Notice entitled "Validated Instructions for Use and Validation Data Requirements for Certain Reusable Medical Devices in Premarket Notifications" (Reprocessing FR Notice, available at https://www.federalregister.gov/documents/2017/06/09/2017-12007/medical-devices-validated-instructions-for-use-and-validation-data-requirements-for-certain-reusable). *Device types identified in the Reprocessing FR Notice represent devices posing a greater likelihood of microbial transmission and represent a high risk of infection. Select "N/A" if the device type in the submission is not included in the Reprocessing FR Notice.*		☐		☐	
			i.	If device types in this submission are included in the Reprocessing FR Notice, the submission includes protocols and test reports for validating the reprocessing instructions. *Select "N/A" if the device type in the submission is not included in the Reprocessing FR Notice.*	☐	☐	☐	
			Comments:					
	26.	The device has a device-specific guidance document, special controls, and/or requirement in a device-specific classification regulation regarding sterility and/or reprocessing that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*			☐		☐	

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

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
		Comments:				
	28.	For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf-life. *Select "N/A" if the device is not provided sterile.*	☐	☐	☐	
		Comments:				
	29.	Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	☐	☐	☐	
		Comments:				
G.	**Biocompatibility** *If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*				☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
	Submission states that there: (*one of the below must be checked*) ☐ Are direct or indirect tissue-contacting components ☐ Are no direct or indirect tissue-contacting components ☐ Information regarding tissue contact status of the device is not provided (if this box checked, please also check one of the two boxes below) ☐ Tissue contact information not needed for this device (e.g., software-only device) ☐ Tissue contact information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "are no" or "not provided and not needed" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information on the tissue-contact status is not provided, and contact information is needed or its contact status is unclear, select "No."* *An example of a direct tissue-contacting device would be an implant that has direct contact with tissues during use. An example of an indirect tissue-contacting device would be fluid entering the body following passing through device/device components not in direct contact with the tissue.*			☐		
	Comments:					
	30.	Submission includes a list identifying each tissue-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	☐	☐		
		Comments:				
	31.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration) for each tissue-contacting device component (e.g., implant, delivery catheter).	☐	☐		
		Comments:				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
	32.	For a biocompatibility assessment of tissue-contacting components, submission includes: • Each relevant endpoint for the device (as identified in device-specific guidance, or Attachment A of the FDA guidance document entitled "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and), has been addressed. • For any testing performed, test protocol (including identification and description of test article including whether the test article is the device in its final finished form using the recommended approach in Attachment F of "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" methods, and pass/fail criteria), and analysis of results (including tables with data points and statistical analyses, where appropriate), as described in Attachment E of the guidance document entitled "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale that considers all relevant endpoints (e.g., materials and manufacturing/processing are identical to the predicate).	☐	☐		
		Comments:				
H.	**Software**					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
	Submission states that the device: (*one of the below must be checked*) ☐ Does contain software/firmware ☐ Does not contain software/firmware ☐ Information on whether device contains software/firmware is not provided (if this box checked, please also check one of the two boxes below) ☐ Software/firmware information not needed for this device (e.g., surgical suture, condom) ☐ Software/firmware information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not contain" or "not provided and not needed" is selected, the software-related criteria below are omitted from the checklist. If information on software is not provided, and this information is needed or the need is unclear, select "No."*			☐		
	Comments:					
	33.	Submission includes a statement of software level of concern and rationale for the software level of concern	☐	☐		
		Comments:				
	34.	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," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale). *Note: This element is also applicable to non-internally generated or off-the-shelf (OTS) software used in the device.*	☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
		Comments:				
I.	**Cybersecurity**					
	Submission states that the device: (*one of the below must be checked*) ☐ Does contain any external wired and/or wireless communication interfaces (Wired: USB, ethernet, SD, CD, RGA, etc. or Wireless: Wi-Fi, Bluetooth, RF, inductive, Cloud, etc.) ☐ Does not contain external interfaces as described above ☐ Information on whether device has external interfaces is not provided (if this box is checked, please also check one of the two boxes below) ☐ Cybersecurity information not needed for this device (e.g., surgical suture, condom) ☐ Cybersecurity information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not contain" or "not provided and not needed" is selected, the cybersecurity criteria below are omitted from the checklist. If information on cybersecurity is not provided, and this information is needed or the need is unclear, select "No."*			☐		
	35.	All applicable documentation identified by the submitter, as described in "Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0. **OR** 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).	☐	☐		
		Comments:				
J.	**Electrical Safety and EMC**					

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

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
	EMC: Submission states that the device: (*one of the below must be checked*) ☐ Does require EMC evaluation ☐ Does not require EMC evaluation ☐ Information on whether device requires EMC evaluation not provided (if this box checked, please also check one of the two boxes below) ☐ EMC information not needed for this device (e.g., surgical suture, condom) ☐ EMC information needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not require" or "not provided and not needed" is selected, the EMC criteria below are omitted from the checklist. If information on EMC is not provided, and it is needed or the need for this information is unclear, select "No."*			☐		
	Comments:					
	37.	Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, a device-specific standard). **OR** Submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☐	☐		
		Comments:				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
K.	**Performance Data General** *If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section L.*					☐	
	Comments:						
	38.	Summaries of the non-clinical laboratory studies and full test reports* are provided. *Summary and full test report content recommendations can be found in FDA's guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket. If a submitter chooses to declare conformity to a voluntary consensus standard that FDA has recognized, submission of a full test report may not be necessary. Refer to 9a. See FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. *Select "N/A" if the submission appropriately does not include performance data or there are no completed tests without a Declaration of Conformity.*		☐	☐	☐	
		a.	Submission includes an explanation of how the data generated from each test supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.). *Select "N/A" if the submission does not include performance data.*	☐	☐	☐	
			Comments:				

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

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

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
L.	**Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))**						
	Submission indicates that device: (*one of the below must be checked*) ☐ Is an in vitro diagnostic device ☐ Is not an in vitro diagnostic device *If "is not" is selected, the performance data-related criteria below are omitted from the checklist.*						
	42.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:					
		a.	Precision/reproducibility	☐	☐	☐	
		b.	Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff).	☐	☐	☐	
		c.	Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).	☐	☐	☐	
		d.	Analytical specificity	☐	☐	☐	
			Comments:				
	43.	The device has a device-specific guidance document, special controls, and/or requirement in a device-specific classification regulation regarding performance data that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*		☐	☐	☐	

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