Contains Nonbinding Recommendations

Acceptance Checklist
for Special 510(k)s

(should be completed within 15 days of DCC receipt)

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

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.

Special 510(k) Criteria **The submission should not be reviewed as a Special 510(k) if "No" is selected for any of the 4 criteria below. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.**		
	Yes	**No**
1. 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.		
Comments:		
2. Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).		
Comments:		
3. Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).		
Comments:		
4. The submission includes only summary-level information (i.e., NO test reports with performance data). *Note that if performance data are provided and are conducted under design validation (21 CFR 820.30(g)), for example, to demonstrate continued conformance with a special control or recognized standard, then a Special 510(k) may be appropriate.*		
Comments:		

Does the submission meet all 4 criteria above?

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

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

Organizational Elements *Failure to include these items along generally should not result in an RTA designation*		
	Yes	**No**
a. Submission contains Table of Contents	☐	☐
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	☐	☐
c. All pages of the submission are numbered *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☐	☐
d. Type of 510(k) is identified– traditional, abbreviated, or special *If type of 510(k) is not designated, review as a traditional*	☐	☐
Comments:		

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
A.	**Administrative**					
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)		☐		☐
		Comments:				
	2.	Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or in 510(k) cover letter):		☐		☐
		a.	Device trade name or proprietary name	☐		☐
		b.	Device common name	☐		☐
		c.	Device class and panel or Classification regulation or	☐		☐

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			Statement that device has not been classified with rationale for that conclusion			
		Comments:				
	3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also and 801.109) *Submitter should use format appropriate for the reviewing Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request the correct format during substantive review.*		☐		☐
		Comments:				
	4.	Submission contains 510(k) Summary or 510(k) Statement *Either a) or b) must be answered "Yes" to be considered complete. Identify any missing element(s) as Comments.*		☐		☐
		a.	Summary contains all elements per 21 CFR 807.92 *See also 510(k) Summary Checklist*	☐	☐	☐
		b.	Statement contains all elements per 21 CFR 807.93	☐		☐
		Comments:				
	5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format. 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).*		☐		☐
		Comments:				
	6.	Submission contains Class III Summary and Certification *See recommended content* *Form should be signed by a responsible person of the firm, not a*		☐	☐	☐

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		consultant. Select "N/A" only if submission is not a Class III 510(k).			
		Comments:			
	7.	If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (FDA Form 3654) or includes detailed information about how and the extent to which the standard has been followed. *There should be a completed form for each referenced national or international standard.* *Select "N/A" only if submission does not reference any standards.*	☐	☐	☐
		Comments:			
	8.	The submission identifies prior submissions for the same device 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. *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.*	☐		☐
		a. 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.	☐		☐

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	• 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**
			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 Agency's current thinking on this topic. *Select "N/A" if the submitter states there were no prior submissions in criterion above.*			
		Comments:				
B.	**Device Description**					
	9.	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. *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.*	☐	☐	☐
		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	☐	☐	☐

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	• 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**
			submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *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.*			
		Comments:				
	10.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
		a.	A description of the principle of operation and mechanism of action for achieving the intended effect.	☐		☐
		b.	A description of proposed conditions of use such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☐		☐
		c.	A list and description of each device for which clearance is requested. *Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, or various sizes, etc.*	☐	☐	☐
		Comments:				
	11.	A description of all device modification(s) including rationale for each modification.		☐		☐
		Comments:				

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	• 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**
	12.	Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions. *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.* *Select "N/A" if the sponsor 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).*			☐	☐	☐
		Comments:				
	13.	If device is intended to be marketed with multiple components, accessories, and/or as part of a system, *Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.*			☐	
		a.	Submission includes a list of all components and accessories to be marketed with the subject device.	☐		☐
		b.	Submission includes a description (as detailed in item #12.a. and b. and 14 above) of each component or accessory. *Select "N/A" if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.*	☐	☐	☐
		c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. *Select "N/A" if the submission states that the component(s)/accessory(ies) does not have a prior 510(k) clearance or the components/accessory(ies) is 510(k) exempt.*	☐	☐	☐

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		Comments:				
C.	**Substantial Equivalence Discussion**					
	14.	Submitter has identified a predicate(s) device		☐		☐
		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. *Information regarding documenting preamendment status is available online (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/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).	☐		☐
		Comments:				
	15.	Submission includes a comparison of the following for the predicate(s) and subject device				
		a.	Indications for use	☐		☐
		b.	Technology, including features, materials, and principles of operation	☐		☐
		Comments:				
	16.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., do not constitute a new intended use, and any differences in technological characteristics are accompanied by information that demonstrates the		☐		☐

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		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)(l)(A) of the FD&C Act) *If there is no difference between the subject and predicate(s with respect to the indications or technology), this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences. 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.*						
		Comments:						
D.	**Design Control Activities**							
	17.	Design Control Activities Summary includes all of the following:						
		a.	Identification of Risk Analysis methods(s) used to assess the impact of the modification on the device and its components AND the results of the analysis			☐		☐
		b.	Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria.			☐		☐
		c.	Declaration of conformity with design controls, including: *All 3 must be present to answer "Yes."*			☐		☐
			i.	Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met.				
			ii.	Statement that manufacturing facility is in conformance with design control				

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				procedure requirements as specified in 21 CFR 820.30			
			iii.	Statement is signed by the individual responsible for these activities			
	Comments:						
E.	**Proposed Labeling (see also 21 CFR part 801)**						
	18.	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			☐		☐
		a.	All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified.		☐		☐
	Comments:						
	19.	Statement that the intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).			☐		☐
	Comments:						

Decision: Accept ___ Refuse to Accept ___

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

Reviewer Signature: _____ Date: _____

Supervisory Signature: _____ Date: _____