

510(k) Submission Checklist

#	Title	Information		Ready	N/A
1	MDUFA Cover Sheet	Medical Device User Fee Amendments (MDUFA) Cover Sheet (<u>Form 3601</u>)			
2	CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Voluntary Cover Sheet (<u>Form 3514</u>)			
3	510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s"			
4	Indications for Use Statement	Use the Indications for Use Statement format in Section D: Form 3881			
5	510(k) Summary or 510(k) Statement	A <u>510(k) Summary</u> or a <u>510(k) Statement</u> is accepted			
6	Truthful and Accurate Statement	Suggested format for the <u>Truthful and</u> <u>Accurate Statement</u>			
7	Class III Summary and Certification	Class III Summary and Certification Format			
8	Financial Certification or Disclosure Statement	 Certification: Financial Interests and Arrangements of Clinical Investigators Disclosure: Financial Interests and Arrangements of Clinical Investigators 	FDA <u>Form</u> 3454 FDA <u>Form</u> 3455		
9	Declarations of Conformity and Summary Reports	 Use of Standards in Substantial Equivalence Determinations FDA Standards program Declaration of conformity Required Elements for Declaration of Conformity to Recognized Standard 	FDA <u>Form</u> 3654		

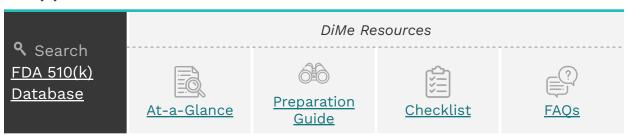
10	Product Description	Provide description of the product's performance specifications and include a brief description of the design requirement. Include diagrams, dimensions, tolerances, and/or schematics (as appropriate).		
11	Executive Summary/ Predicate Comparison	 Executive summary should include: Concise description of the product (with indications for use and technology) Product comparison table Concise summary for any performance testing in the submission Learn more 		
12	Substantial Equivalence Discussion	Demonstrate the substantial equivalence for: Indications for use Technology Performance specifications, including any testing Learn more		
13	Proposed Labeling	#G911-1, FDA 89-4203 and Guidance on Medical Device Patient Labeling		
14	Sterilization/ Shelf Life	For products sold as <u>sterile</u> or <u>reprocessed</u> single use products		
15	Biocompatibility Biocompatibility assessment of tissue-contacting components or a statement (biocompatibility testing is not needed as long as a rationale is provided)			
16	Software	Guidance for the <u>Content of Premarket</u> <u>Submissions for Software Contained in</u> <u>Medical Devices</u>		
17	Electromagnetic Compatibility and Electrical Safety	 CDRH Medical Device <u>Electromagnetic Compatibility Program</u> Also see IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance or an equivalent method 		
18	Performance Testing – Bench	Non-clinical bench performance testing – recommended content and format		

19	Performance Testing – Animal	Animal testing results that support the performance characteristics of the product	
20	Performance Testing – Clinical		
21	Disclosure	<u>Certification form</u> and <u>Financial Disclosure</u> <u>form</u>	
22	Kit Certification	For review purpose: <u>Kit certification for</u> <u>premarket notification (510(k))</u>	

Note: The following information is not intended to serve as a comprehensive review. The FDA recommends that the submitter include this completed checklist as part of the application. The guidance includes acceptance checklists for each type of 510(k) submission:

- Traditional 510(k) Checklist
- Abbreviated 510(k) Checklist
- Special 510(k) Checklist

510(k) Toolkit



Access DiMe's Digital Health Regulatory Pathway Resources





