510(k) Submission Checklist

Digital Health **Regulatory Pathways**

#	Title	Information		Ready	N/A
1	**MDUFA Cover Sheet**	Medical Device User Fee Amendments (MDUFA) Cover Sheet (Form 3601)		☐	☐
2	**CDRH Premarket Review Submission Cover Sheet**	CDRH Premarket Review Submission Voluntary Cover Sheet (Form 3514)		☐	☐
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 510(k) Summary or a 510(k) Statement is accepted		☐	☐
6	**Truthful and Accurate Statement**	Suggested format for the Truthful and Accurate Statement		☐	☐
7	**Class III Summary and Certification**	Class III Summary and Certification Format		☐	☐
8	**Financial Certification or Disclosure Statement**	1. **Certification**: Financial Interests and Arrangements of Clinical Investigators 2. **Disclosure**: Financial Interests and Arrangements of Clinical Investigators	FDA Form 3454 FDA Form 3455	☐	☐
9	**Declarations of Conformity and Summary Reports**	1. Use of Standards in Substantial Equivalence Determinations 2. FDA Standards program 3. Declaration of conformity 4. Required Elements for Declaration of Conformity to Recognized Standard	FDA Form 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 sterile or reprocessed 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 Content of Premarket Submissions for Software Contained in Medical Devices	☐	☐
17	**Electromagnetic Compatibility and Electrical Safety**	1. CDRH Medical Device Electromagnetic Compatibility Program 2. 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**	Certification form and Financial Disclosure form	☐	☐
22	**Kit Certification**	For review purpose: Kit certification for premarket notification (510(k))	☐	☐

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

Search FDA 510(k) Database	*DiMe Resources*			
	 At-a-Glance	 Preparation Guide	 Checklist	 FAQs

Access DiMe's Digital Health Regulatory Pathway Resources

 **Identify** your regulatory pathway

 **Build** your regulatory strategy

 **Interact** with regulators