# 510(k) Submission Checklist

<table>
<thead>
<tr>
<th>#</th>
<th>Title</th>
<th>Information</th>
<th>Ready</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>MDUFA Cover Sheet</td>
<td>Medical Device User Fee Amendments (MDUFA) Cover Sheet (Form 3601)</td>
<td>☐</td>
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</tr>
<tr>
<td>2</td>
<td>CDRH Premarket Review Submission Cover Sheet</td>
<td>CDRH Premarket Review Submission Voluntary Cover Sheet (Form 3514)</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3</td>
<td>510(k) Cover Letter</td>
<td>Appendix A of “Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s”</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>4</td>
<td>Indications for Use Statement</td>
<td>Use the Indications for Use Statement format in Section D: Form 3881</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>5</td>
<td>510(k) Summary or 510(k) Statement</td>
<td>A 510(k) Summary or a 510(k) Statement is accepted</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>6</td>
<td>Truthful and Accurate Statement</td>
<td>Suggested format for the Truthful and Accurate Statement</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>7</td>
<td>Class III Summary and Certification</td>
<td>Class III Summary and Certification Format</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
| 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 | ☐     | ☐   |
<table>
<thead>
<tr>
<th></th>
<th><strong>Product Description</strong></th>
<th>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).</th>
</tr>
</thead>
</table>
| 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  
[Learn more](#) |
| 14 | **Sterilization/Shelf Life** | For products sold as [sterile](#) or [reprocessed](#) single use products  
[Learn more](#) |
| 15 | **Biocompatibility** | Biocompatibility assessment of tissue-contacting components or a statement (biocompatibility testing is not needed as long as a rationale is provided)  
[Learn more](#) |
| 16 | **Software** | Guidance for the [Content of Premarket Submissions for Software Contained in Medical Devices](#)  
[Learn more](#) |
| 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  
[Learn more](#) |
| 18 | **Performance Testing – Bench** | [Non-clinical bench performance testing](#) – recommended content and format  
[Learn more](#) |
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

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**510(k) Toolkit**

<table>
<thead>
<tr>
<th>Search FDA 510(k) Database</th>
<th>DiMe Resources</th>
</tr>
</thead>
<tbody>
<tr>
<td>At-a-Glance</td>
<td>Preparation Guide</td>
</tr>
<tr>
<td></td>
<td>Checklist</td>
</tr>
<tr>
<td></td>
<td>FAQs</td>
</tr>
</tbody>
</table>

Access DiMe's Digital Health Regulatory Pathway Resources

- Identify your regulatory pathway
- Build your regulatory strategy
- Interact with regulators