510(k) Preparation Guide

Digital Health
Regulatory
Pathways

The 510(k) submission process is a type of premarket submission used by the US Food and Drug Administration (FDA) to evaluate the safety and effectiveness of digital health products. In order to make a 510(k) submission, an organization must provide the FDA with information demonstrating that their digital health product is substantially equivalent to a digital health product already on the market, known as a "predicate device."

DOWNLOAD **At-a-Glance Overview on 510(k)**

What should I know?

The 15 step process as a general guide for preparing a FDA 510(k) submission:

1. Determine if your digital health product is subject to the 510(k) process.
2. Identify the intended use of the digital health product and determine if it is subject to premarket notification (510(k)) requirements.
3. Identify a suitable predicate device to compare your digital health product to.
4. Assemble a team of knowledgeable individuals to assist with the submission process.
5. Gather all necessary information and documentation about your digital health product, including design and intended use, clinical data, nonclinical testing data, final product specifications, manufacturing information, and quality system information.
6. Prepare a cover letter and table of contents for the submission.
7. Write an executive summary outlining the key points of the submission.
8. Describe the digital health product in detail, including a comparison to the predicate device(s) and any differences between the products.
9. Include any relevant clinical data and published literature in the submission.
10. Provide nonclinical testing data to demonstrate the safety and effectiveness of the digital health product.
11. Include the product's labeling and instructions for use.
12. Submit any necessary photographic or illustrative materials.
13. Provide final product specifications and manufacturing information.
14. Include information about your quality system.
15. Submit any additional information requested by the FDA.

It is important to carefully and thoroughly complete all required sections of the 510(k) submission in order to increase the chances of obtaining FDA clearance to market your digital health product.

How is the 510(k) submission process different from De Novo submission?

Differences between 510(k) and De Novo:

Category	510(k)	De Novo
FDA Oversight Language	Cleared	Granted
Risk	Low to Moderate	Low to Moderate
Medical Device Product Class	Class I, II	Class I, II
Control	General Controls Special Controls	General Controls Special Controls
Safety	No Substantial Equivalence	Reasonable Assurance of Safety
Effectiveness		Reasonable Assurance of Effectiveness
Clinical Data	10-15% require clinical data	Yes
Timeline	90 days (traditional)	150 days
Cost	Standard Fee: $12,745 Small Business Fee: $3,186	Standard Fee: $132,464 Small Business Fee: $33,116
Annual reporting requirement	No	No
GMP (Good Manufacturing practice) requirement	No	Yes
MDR (Medical Device reporting) requirement	No	Yes
Examples	TBD	TBD

Note: Some digital health products can be 510(k) exempt as well, meaning they do not require FDA oversight.

DOWNLOAD **Comparison Chart of Regulatory Pathways for Digital Health**

What should I include?

General items to consider to prepare for an FDA 510(k) submission:

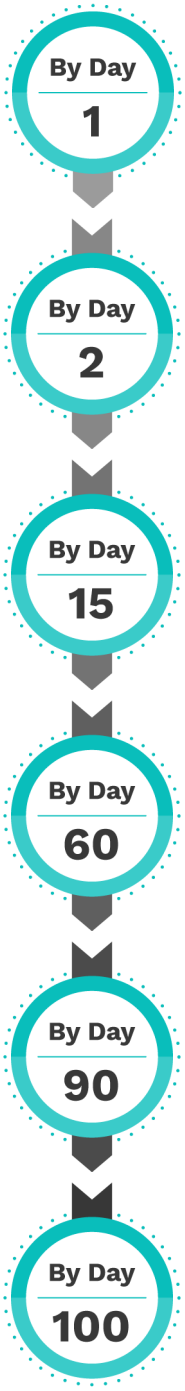
- **Cover letter**: This document should include the name and contact information of the manufacturer, as well as a brief summary of the digital health product and the reason for the submission.
- **Table of contents**: This document should list all the documents and information included in the submission.
- **Executive summary**: This document should provide an overview of the digital health product device, including its intended use and function, and a summary of the data and information provided in the submission.
- **Device description**: This document should include detailed information about the digital health product, including its design, materials, size, and other relevant characteristics.
- **Indications for use**: This document should describe the specific conditions or situations in which the digital health product is intended to be used.
- **Comparison to predicate device**: This document should describe how the digital health product is substantially equivalent to the predicate device, including a comparison of their intended use, design, and performance.
- **Preclinical testing**: This document should describe any preclinical testing that has been conducted on the digital health product, including results and any relevant data.
- **Clinical data**: This document should include any clinical data that has been collected on the digital health product (like clinical trials or studies results).
- **Labeling**: This document should include the proposed labeling for the digital health product, including instructions for use, warning statements, and any other relevant information.
- **Software validation**: If the digital health product includes software, this document should describe the validation process that has been conducted to ensure the software is safe and effective.
- **Product history**: This document should include a history of the digital health product, including any previous submissions or changes to the product.
- **Environmental assessment**: This document should describe any potential environmental impacts of the digital health product and any measures that have been taken to mitigate those impacts.

The list above is not exhaustive and the specific information and documents required for a 510(k) submission may vary depending on the digital health product and the nature of the submission. It's important to carefully review the FDA's guidance on 510(k) submissions to ensure that all necessary information is included in the submission.

DOWNLOAD **510(k) Submission Checklist**

What is the FDA 510(k) process timeline?

The submission process timeline for Traditional and Abbreviated 510(k)s



FDA receives 510(k) application

The applicant submits the 510(k) application to the FDA.

FDA sends acknowledgement or hold letter

The FDA will hold the submission if there are unresolved issues with the User Fee/eCopy.

FDA conducts Acceptance Review.

The FDA will inform the requester if their application has been accepted for Substantive Review or placed on RTA hold.

FDA conducts Substantive Review.

The FDA will determine if the application can be completed via interactive review or if it will be placed on hold pending provision of additional information.

FDA sends the decision

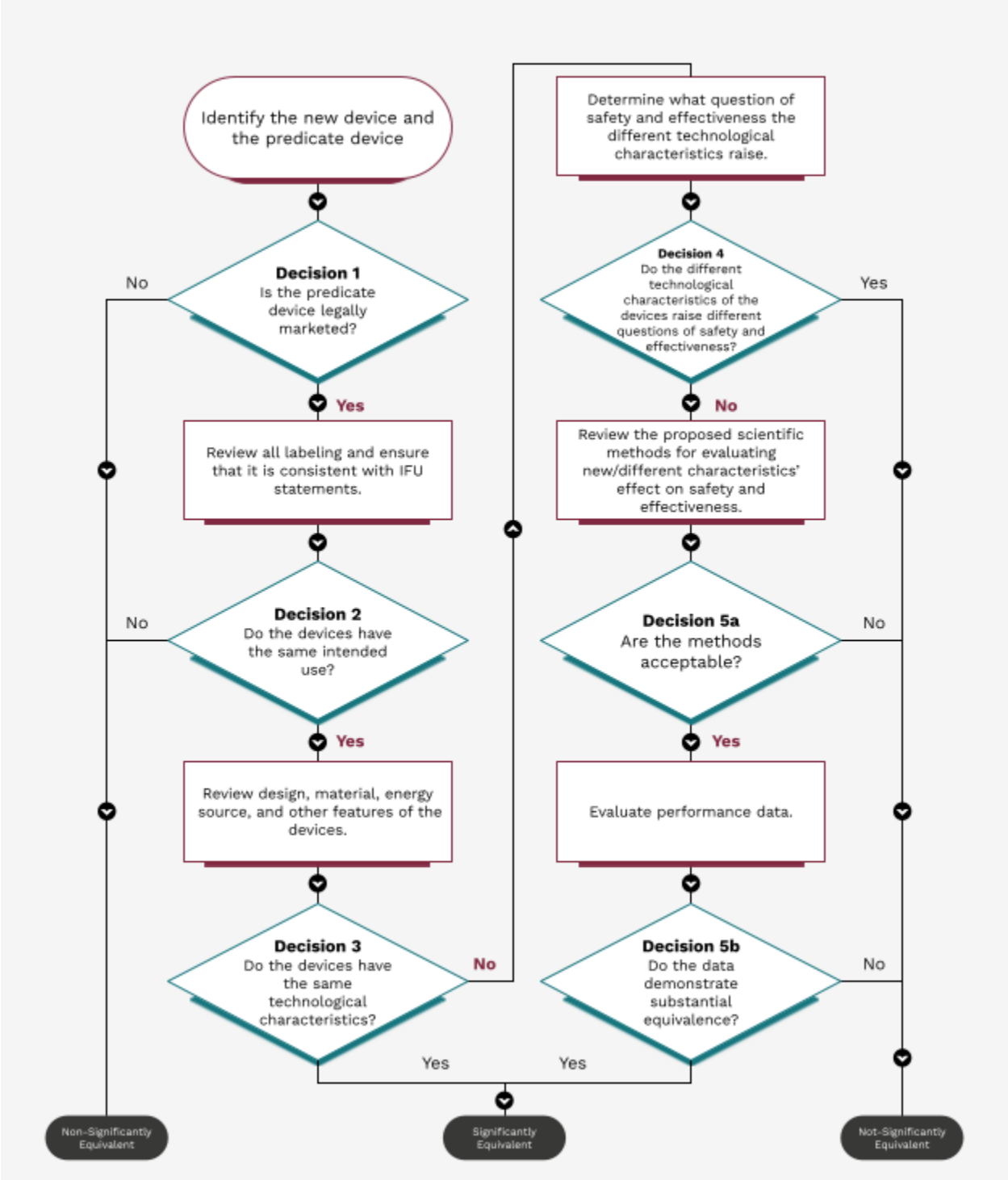
The FDA will send their final MDUFA decision on the 510(k) submission to the applicant via email.

In case of delay

If the decision is not reached by the 100th day, the FDA will provide the requester with written feedback and explain why a decision has not been reached.

Note: The above timeline shown is for Traditional and Abbreviated 510(k)s, which have a 90-day review time. Special 510(k)s have a 30-day review time.

How to determine “substantial equivalence”



DOWNLOAD **510(k) Decision Making Flowchart**

Additional information

- Deciding When to Submit a 510(k) for a Software Change to an Existing Device
- Deciding When to Submit a 510(k) for a Change to an Existing Device
- Required Submission of Safety and Effectiveness Information for Certain Class III Devices
- Refuse to Accept Policy for 510(k)s
- The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications
- Premarket Notification 510(k)
- FDA Reclassification Process

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