FAQs for **510(k)**

Digital Health
Regulatory
Pathways

1 Who is a 510(k) typically required for?

A 510(k) is typically required to submit in four cases:

- Domestic manufacturers introducing a digital health product to the U.S. market.
- Specification developers introducing a digital health product to the U.S. market.
- Repackers or relabelers who make labeling changes or whose operations significantly affect the digital health product.
- Foreign manufacturers/exporters or U.S. representatives of foreign manufacturers/exporters introducing a device to the U.S. market.

2 When a 510(k) is typically required?

A 510(k) is typically required when:

- Introducing a device into commercial distribution (marketing) for the first time (unless exempt or not marketed before May 28, 1976).
- There is a change or modification to a legally marketed device and that change could significantly affect its safety or effectiveness.

3 What are some cases when a 510(k) is not required?

- Your firm sells unfinished products to another firm for further processing, or sells components to be used in the assembling of devices by other firms. However, if your components are to be sold directly to end users as replacement parts, a 510(k) is required.
- Your product is not being marketed or commercially distributed. You do not need a 510(k) to develop, evaluate, or test a device, including clinical evaluation. Please note that if you perform clinical trials with your device, you are subject to the Investigational Device Exemption (IDE) regulation.
- You distribute another firm's domestically manufactured product. You may place a label on the product, "Distributed by ABC Firm" or "Manufactured for ABC Firm," and sell it to end users without submission of a 510(k).
- You are a repackager or a relabeler and the existing labeling or condition of the device is not significantly changed (in most cases). The labeling should be consistent with the labeling submitted in the 510(k) with the same indications for use, warnings, and contraindications.

- Your product was legally in commercial distribution before May 28, 1976 and has not been significantly changed or modified in design, components, method of manufacture, or intended use. These devices are "grandfathered" and you have Preamendment Status.
- The product is made outside the U.S. and you are an importer of the foreign made medical device. A 510(k) is not required if a 510(k) has been submitted by the foreign manufacturer and received marketing clearance. Once the foreign manufacturer has received 510(k) clearance for the device, the foreign manufacturer may export their device to any U.S. importer.
- Your device is exempted from 510(k). Certain Class I or II devices can be marketed for the first time without having to submit a 510(k). A list of the Class I and II exempt devices can be found on Medical Device Exemptions 510(k) and GMP Requirements.

4 Do I need to register my facility before I submit a 510(k)?

No – If you are a new company and do not manufacture any digital health product, you should not register until you are within 30 days of manufacturing and distributing the product. The 510(k) submission should state that you are not currently registered. Information on how to register your facility is available at Registering Your Establishment.

5 I would like to distribute a manufacturer's product under my own company name. Do I need to submit a 510(k)?

No – The manufacturer should submit the 510(k), if required for the product. As required under 21 CFR 801.1(c), where a product is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase that reveals the connection such person has with such product, such as "Manufactured for ABC Company," "Distributed by ABC Company," or any other wording that expresses the facts. The distributor should forward all product complaints to the manufacturer for evaluation in accordance with 21 CFR 820.198 Complaint files.

6 Do I need to provide documentation that my facility complies with the Quality System in my 510(k)?

No – There is no pre-approval inspection as a prerequisite to 510(k) clearance. However, you should be prepared for an FDA inspection at any time.

7 Do I need to have my facility inspected according to the Quality System regulations before I submit a 510(k)?

No – There is no pre-approval inspection as a prerequisite to 510(k) clearance. However, you should be prepared for an FDA inspection at any time

8 Do I need to submit a 510(k) if I make changes to my digital health product?

Maybe - A premarket notification [510(k)] is required when a legally marketed product subject to 510(k) requirements is significantly changed or modified in design, components, method of manufacture, or intended use. Significant changes or modifications are those that could significantly affect the safety or effectiveness of the product, or major changes or modifications in the intended use of the product.

A product that has been in commercial distribution or is being reintroduced into commercial distribution that has been significantly changed or modified in design, components, method of manufacturer, or intended use may require a 510(k). The following constitutes significant changes or modification that would require a 510(k):

- A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.
- A major change or modification in the intended use of the device.

Learn more: Is a new 510(k) required for a modification to the device? | FDA and Deciding When to Submit a 510(k) for a Change to an Existing Device.

9 What are examples of information for the 510(k) submission that product innovators commonly miss?

Some of the commonly missed information needed as a part of the 510(k) submission includes:

- Inadequate product description
- Discrepancies throughout submission (most often related to product description or indications for use)
- Problems with indications for use
- Failure to follow or otherwise address current guidance document(s) or recognized standards
- Performance testing required for certain product types is completely missing (i.e., no performance data provided at all)
- Clinical data required for certain product types is completely missing (i.e., no clinical data provided at all)

10 Can foreign companies submit a Premarket Notification 510(k)?

Yes – The foreign manufacturer may submit a 510(k) directly to the FDA. For convenience, a foreign manufacturer may receive assistance from a U.S. entity and may use a contact person residing in the U.S.

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