510(k) At-a-Glance

Digital Health **Regulatory Pathways**

What is a 510(k)?

A 510(k), also known as a premarket notification, is a marketing clearance application for a digital health product to get an FDA clearance to market the product. It allows FDA to determine **substantial equivalence**.

What is substantial equivalence (SE)? SE is present when a new digital health product demonstrates similarity to a **predicate device** and has:

1. The same intended use *and* the same technological characteristics, *OR*
2. Differences in technological characteristics that do not raise different questions regarding safety and effectiveness

What is a predicate device? A predicate device is a legally marketed device, usually previously cleared through the 510(k) process, that is used for comparison to a new device for the purpose of determining substantial equivalence.

When is a 510(k) typically required?

1. When introducing a new digital health product to the market for the first time
2. When changing the indications for use of a previously cleared digital health product
3. When making significant modification(s) to a previously cleared digital health product

What kind of digital health product does not need a 510(k)?

Class I and II devices. Most, but not all, class I and II devices are exempt from 510(k).

What does "exempt from 510(k)" mean? When a digital health product doesn't need a 510(k) clearance prior to marketing the product, it's known as "exempt from 510(k)." These situations include products that are substantially equivalent to a predicate device that is already legally marketed, or products that are for investigational use only.

What are types of 510(k) submissions?

Traditional 510(k)

- Relies on the demonstration of substantial equivalence
- The Traditional 510(k) method can be used under any circumstance

Abbreviated 510(k)

- Relies on the use of guidance documents, special controls, and recognized standards
- Under certain conditions, sponsors may not need to submit test data in an Abbreviated 510(k)

	Special 510(k)	• Device modification to manufacturer's own legally marketed device • Modification does NOT affect the intended use or fundamental scientific technology of the device • No data is evaluated by FDA
How long does the process take?	**Traditional 510(k)**	90 days
	Abbreviated 510(k)	90 days
	Special 510(k)	30 days
How much does it cost to receive 510(k) clearance?*		• **Standard Fee** $12,745 • **Small Business Fee** $3,186
Where can I access 510(k) cleared products?		Check out a list of legally marketed products in the 510(k) database.

How can I establish substantial evidence for my digital health product?		Ask these 4 questions:
		1. Is the predicate device legally marketed?
		2. Do the devices have the same intended use?
		3. Do the devices have the same technological characteristics?
		4. Do the different technological characteristics of the devices raise different questions of safety and effectiveness?
		  ○ Are the methods acceptable?
		  ○ Do the data demonstrate substantial equivalence?

**510(k) Fees: All types of 510(k)s (Traditional, Abbreviated, and Special) are subject to the user fee. However, there is no user fee for 510(k)s submitted to the FDA on behalf of an FDA-accredited third-party reviewer.*

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