De Novo At-a-Glance

Digital Health **Regulatory Pathways**

What is a De Novo Classification Request?

The De Novo Classification Request provides a marketing pathway (other than the 510(k) pathway) to classify novel, low-risk digital health products that provide a reasonable assurance of safety and effectiveness for their intended use, but for which there is no legally marketed **predicate device**. It's a process by which novel products are classified as a FDA Class I or Class II medical device (considered to have low to moderate risk), instead of being automatically assigned Class III (considered to have high risk), which some of these products do not fall into.

What is a Predicate Device? 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 De Novo typically required?

A De Novo request can be submitted with or without a preceding 510(k). There are two typical scenarios in which one can submit a De Novo request:

- **Scenario A**: After receiving a **not substantially equivalent (NSE)** determination (that is, there is no predicate device, or the product has a new intended use or different technological characteristics that raise different questions of safety and effectiveness) in response to a 510(k) submission.
- **Scenario B**: If you've determined, after extensive research, that there is no legally marketed device on which to base a determination of substantial equivalence.

What is a Not Substantially Equivalent (NSE) designation? An NSE designation applies when a new digital health product **does not** demonstrate similarity to a predicate device. The new product has:

1. A different intended use *and/or* different technological characteristics, *OR*
2. Differences in technological characteristics that raise different questions regarding safety and effectiveness

What kind of products qualify for a De Novo?

1. Novel, lower- to medium-risk digital health products
2. Novel products that do not have:
    a. Existing classification
    b. A substantial equivalence determination
    c. A predicate device found in the market
3. Products that meet FDA Class I or II medical device requirements based on risk-benefit analysis

How long does the process take?	**Administrative Review**	15 days
	Technical Review	120 days
	Respond to FDA Queries	180 days
	Publication in the Federal Register	30 days

How much does the process cost?*

- **Standard Fee** $132,464
- **Small Business Fee*** $33,116

Where can I access De Novo classified products?

Check out a list of legally marketed products in the De Novo database.

How can I provide reasonable assurance of safety and effectiveness for my digital health product?

1. Determine if the product's probable benefits outweigh probable risks
2. Identify all the product's probable risks to health
3. Determine level of regulatory controls needed:
    - If Class I – only general controls
    - If Class II – general and special controls

** Small Business Fee: For businesses certified by the FDA Center for Devices and Radiological Health (CDRH) as a small business.*

De Novo Toolkit

Search FDA De Novo 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