FAQs for **De Novo Pathway**

Digital Health Regulatory Pathways

1 What does "De Novo" stand for?

De Novo is a Latin term [Latin, Anew (ə-noō′, ə-nyoō′)] that means, "A second time; over again; once more." The Latin definition fits with the FDA's use of the term to illustrate a branch of regulatory oversight addressing requests for new digital health product or technology where there is no comparable "predicate device" in the market.

2 What kind of digital health products are eligible for a De Novo request?

Digital health products that are not substantially equivalent to any legally marketed predicate device and are classified as Class III (high-risk) are eligible for a De Novo request. The device must be novel and not pose an unreasonable risk to the public health.

3 What are the advantages of a De Novo Request?

The advantage of a De Novo request include a lower-risk classification for the product, which can lead to less stringent regulatory requirements and a faster route to market access. Additionally, a device with a De Novo classification can serve as a predicate device for one's future products.

4 Can a De Novo request and a 510(k) request be filed at the same time?

No – Upon receipt of a De Novo submission, the FDA will search their database to see if any submissions for your product are in process. If they find you have submitted your device for review under a 510(k) for the same intended use, they will reject the De Novo submission.

5 Should "Pre Sub" be considered before submitting a De Novo Request?

Yes – the FDA strongly recommends filing a "Pre Submission" if no products similar to yours have been reviewed via the 510(k) process.

6 How long does the process of a De Novo request take?

Under the Medical Device User Fee and Modernization Act (MDUFA) IV, the FDA's goal is to make a decision about a De Novo request in **150 review days.**

7 What is the FDA track record in reviewing a De Novo Request?

From 2019 to 2022, the track record for the products granted under De Novo classification is as below:

Year	# of De Novo Granted	Average Duration	150-day%
2019	21	307 days	23.8%
2020	26	301 days	11.5%
2021	30	360 days	3.3%
2022	17	394 days	11.8%

Source: Medical Device Academy

8 Is there a fee associated with a De Novo request?

Yes – For 2022, the standard user fee is $132,464 and the small business fee is $33,116. The fees are determined by fiscal year. Check out the most updated fee information here.

9 When may the FDA refuse to accept a De Novo request?

The FDA may refuse to accept a De Novo request because:

1. There is an existing open or pending submission [510(k), PMA, etc.] or reclassification petition for the same product or indication of use.
2. The De Novo request is incomplete or does not follow the proper format.
3. The De Novo request is for more than one type of digital health product.
4. The submitting company has not responded to (or justified) a previous deficiency communicated by the FDA.

10 Can a De Novo request be withdrawn or modified?

Yes – A De Novo request can be withdrawn or modified for a submitted request before a decision is made by the FDA.

11 What are common reasons for the FDA declining a De Novo request?

Common reasons FDA will decline a De Novo request include:

Ineligibility

- Not a medical device/combination product
- Product is already classified or is already approved via Premarket Approval process

General

- Product doesn't meet criteria for classification into Class I or II
- Omission or false statement of material
- Labeling noncompliance

Data

- The probable benefits do not outweigh the probable risks for the product
- General and/or special controls are insufficient to provide reasonable assurance of safety and effectiveness, or the data provided in the request are insufficient to determine whether general controls or general and special controls can provide a reasonable assurance of safety and effectiveness of the device
- A clinical or nonclinical study was either not completed per protocol or deficiencies related to the study were not justified or adequately addressed
- Requester made significant unsolicited changes to product's indications of use or technological characteristics after acceptance of a De Novo request

12 Can a De Novo request be appealed if it is denied?

Yes – A De Novo request can be appealed if it is denied by the FDA.

13 What happens after a De Novo request is granted?

After a De Novo request is granted, the device will be reclassified into a lower-risk class and the manufacturer will be required to comply with the regulatory requirements for that class.

14 Can a digital health product that has been granted a De Novo classification be reclassified in the future?

Yes – A product that has been granted a De Novo classification can be reclassified in the future if new information or data becomes available that affects the risk-benefit profile of the product.

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