De Novo Preparation Guide

Digital Health
Regulatory Pathways

The De Novo Classification request is a type of premarket submission (marketing authorization) used by the US Food and Drug Administration (FDA) for products that have no legally marketed predicate device to which they can be compared in order to be classified as substantially equivalent. It allows manufacturers to request that the FDA reclassify their product into a lower-risk class.

DOWNLOAD At-a-Glance Overview on De Novo Request

What should I know?

The 15 step process as a general guide for preparing a FDA De Novo request submission:

1. Identify the intended use of the device and determine if it meets the criteria for a De Novo classification.
2. Review FDA guidance documents relevant to the device and its intended use.
3. Determine if any similar devices have been granted De Novo clearance or classification and review their submissions.
4. Assemble a team of experts, including a regulatory affairs consultant, to assist with the submission.
5. Develop a detailed design history file for the device, including design inputs, outputs, and verification and validation testing.
6. Conduct risk analysis and develop a risk management plan.
7. Prepare a detailed technical report that describes the device, its intended use, and the results of testing and evaluation.
8. Prepare a detailed clinical evaluation report, if applicable.
9. Prepare a detailed labeling and user manual for the device.
10. Prepare a detailed submission cover letter that summarizes the device, its intended use, and the information provided in the submission.
11. Prepare and submit a Form FDA 356h (De Novo request) and all supporting documentation, including the design history file, technical report, clinical evaluation report, labeling, and user manual.
12. Wait for the FDA to review the submission and request additional information, if needed.
13. Respond to any requests for additional information in a timely manner.
14. Attend a pre-submission meeting with the FDA, if requested.
15. Wait for the FDA to make a final decision on the De Novo request.

Please note that this is a general guide and may vary depending on the specific product(s) and circumstances. It is important to carefully and thoroughly complete all required sections of the De Novo submission in order to increase the chances of obtaining FDA clearance to market your digital health product. Prior to submitting a De Novo request to the FDA, here are a few recommendations:

1. Consider submitting a **Pre-Submission** (Pre-Sub) to obtain feedback from the appropriate premarket review division.
2. Consult an **FDA regulatory expert** (e.g., onboard an advisor or consultant or hire a regulatory expert) to help plan and execute a request on your behalf.

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

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

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

What should I include?

General items to consider to prepare for a FDA De Novo request:

Note: Colored text represents De Novo classification-specific elements

- CDRH Premarket Review Submission Cover Sheet
- Table of contents
- Administrative information
- Regulatory history
- Product name
- Indication of use
- Product description
- Alternate practices and procedures
- Classification of summary
- Summary of risk and mitigations
- Proposed special controls
- Classification recommendations
- Standards
- Summary of studies
- Benefits and risk considerations
- Technical sections:
  - Non-clinical testing
  - Software
  - Clinical testing
- Other information:
  - Bibliography
  - Other information reasonably known to the requester
  - Other information to support reasonable assurance of safety and effectiveness
- Samples (if requested)
- Labeling

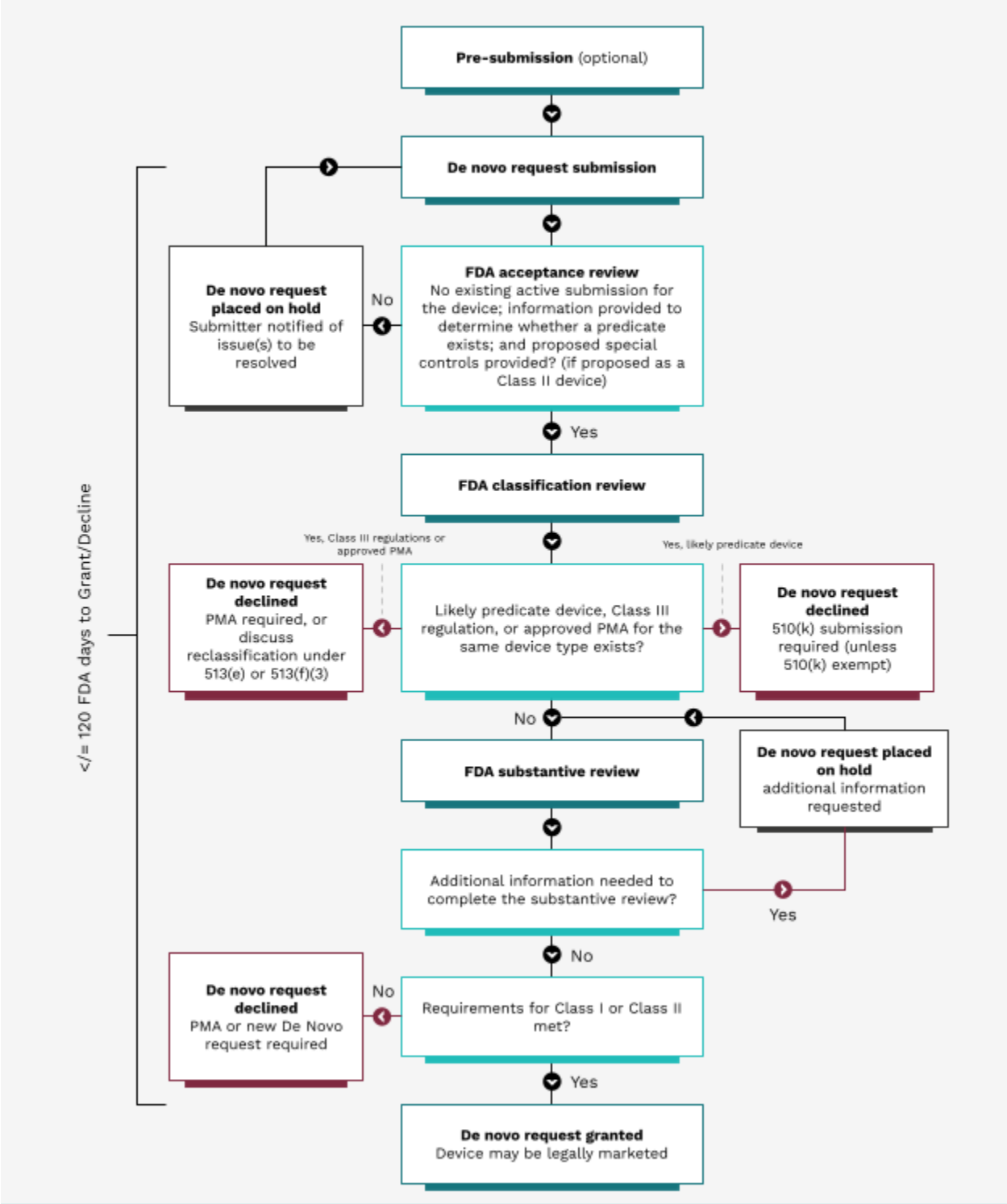
The list above is not exhaustive and is a general list of things to prepare for the De Novo request. The FDA may refuse to accept a De Novo request if:

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 request is incomplete or does not follow the proper format.
3. The request is for more than one type of digital health product.
4. The requesting company has not responded to a previous deficiency communicated by the FDA.

It's important to carefully review the FDA's guidance on De Novo requests to ensure that all necessary information is included in the submission.

DOWNLOAD **Submission Checklist for De Novo Request**

What is the FDA De Novo request review process?



DOWNLOAD De Novo Request Review Process

What should I expect?

Outcomes to expect for an FDA De Novo request decision:

Based on the information provided by the company for their digital health product, the FDA will assess for a reasonable assurance of safety and effectiveness and to determine if the probable benefits of the product outweigh the probable risks. The results could be as follows:

- The FDA will **grant** the De Novo request – if the probable benefits of the product outweigh the probable risks and the controls (general and/or special controls) are adequate to demonstrate it.
- The FDA will **decline** the De Novo request – if the controls (general and/or special controls) do not provide reasonable assurance of safety and effectiveness and the probable benefit does not outweigh the probable risk for the product.

Granted

If the FDA grants a De Novo request:

- The new product is authorized to be marketed. It must now comply with applicable regulatory controls.
- A new classification regulation is established for the product.
- The new product can be used as a predicate for future 510(k) submissions, when applicable.
- The FDA publishes in the Federal Register a notice announcing the new classification regulation and, for Class II devices, the new special controls.
- The FDA generates and publicly discloses a decision summary and posts a copy of the granting order notifying the requester about marketing authorization.

Declined

If the FDA declines a De Novo request:

- The declined request is likely due to the FDA determining that general and/or special controls are insufficient to provide reasonable assurance of the safety and effectiveness of the product, or the data provided in the request are insufficient to determine the above.
- The product will remain as an FDA Class III product and shall not be legally marketed.
- The FDA will issue a written order with an explanation about the reasons for the request denial.
- For next steps, the product must either be approved via the PMA pathway, or additional information can be collected and re-submitted with a “new” De Novo request.

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