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FDA De Novo Authorization procedure

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Overview of the De Novo Pathway

The De Novo Classification process allows manufacturers to obtain a Class I or II classification for new devices that do not have a legally marketed predicate device or that have received a "Not Substantially Equivalent" (NSE) determination in a 510(k), but present a low or moderate risk. In the absence of a suitable predicate, these devices could automatically be classified as high risk (Class III), requiring PMA (Premarket Approval). However, the De Novo process offers a more appropriate pathway for products that do not meet the Class III risk level.

What is a De Novo Classification Request?

A De Novo classification request is a risk-based process used by the FDA to classify devices according to the Federal Food, Drug, and Cosmetic (FD&C) Act criteria. Devices are classified into class I if general controls suffice for safety and effectiveness, class II if special controls are needed beyond general ones, and class III if there's insufficient information for class I or II, especially for life-sustaining devices or those posing a significant health risk.

Risk-based Classification process

Class I

If general controls suffice for safety and effectiveness

Class II

If special controls are needed

Class III

If there's insufficient information for class I or II, especially for life-sustaining devices or those posing a significant health risk

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When should a De Novo be considered?

The De Novo process is applicable when:

De Novo

There is no appropriate "predicate" device for the 510(k).

De Novo

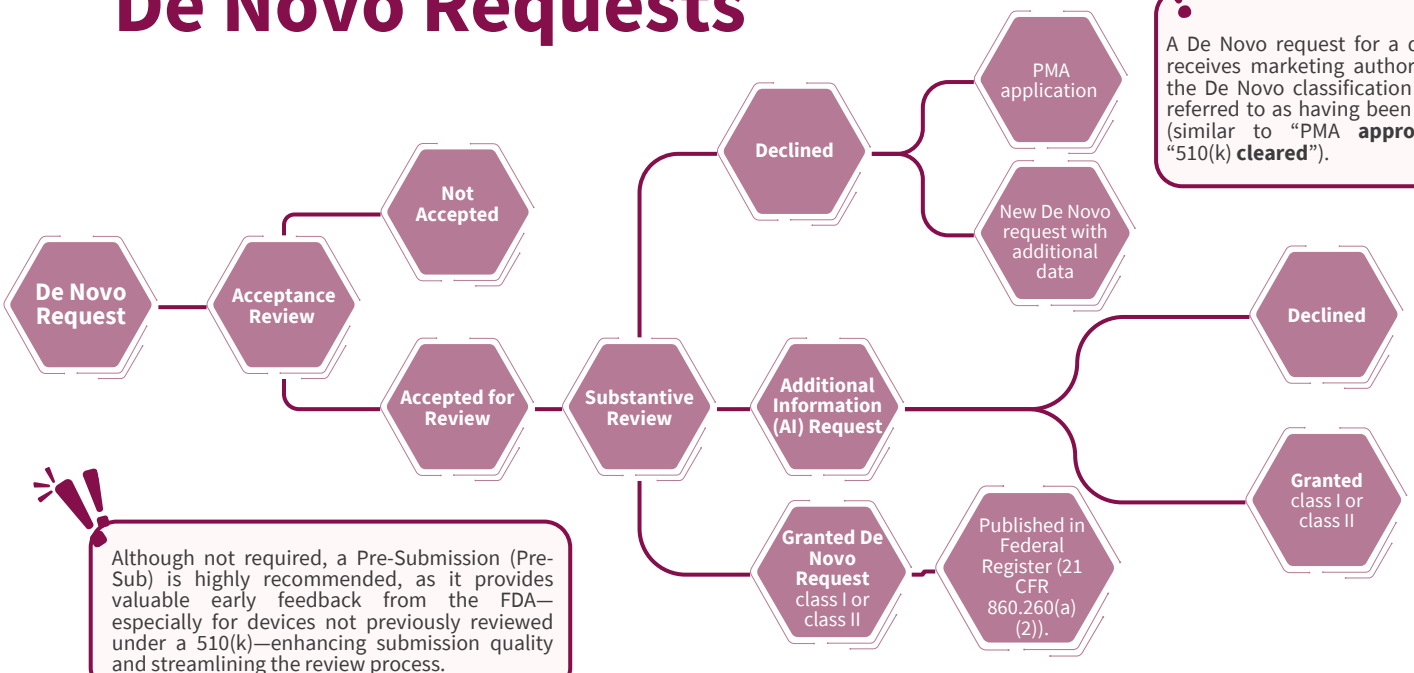
NSE determination has been obtained on a 510(k).

De Novo

Risk of the device is considered moderate or low and general or special controls may be established.

If the FDA grants De Novo classification, the product will be eligible for 510(k) clearance in the future, when applicable.

Review Process for De Novo Requests



A De Novo request for a device that receives marketing authorization via the De Novo classification process is referred to as having been "**granted**" (similar to "PMA **approved**" and "510(k) **cleared**").

Although not required, a Pre-Submission (Pre-Sub) is highly recommended, as it provides valuable early feedback from the FDA—especially for devices not previously reviewed under a 510(k)—enhancing submission quality and streamlining the review process.

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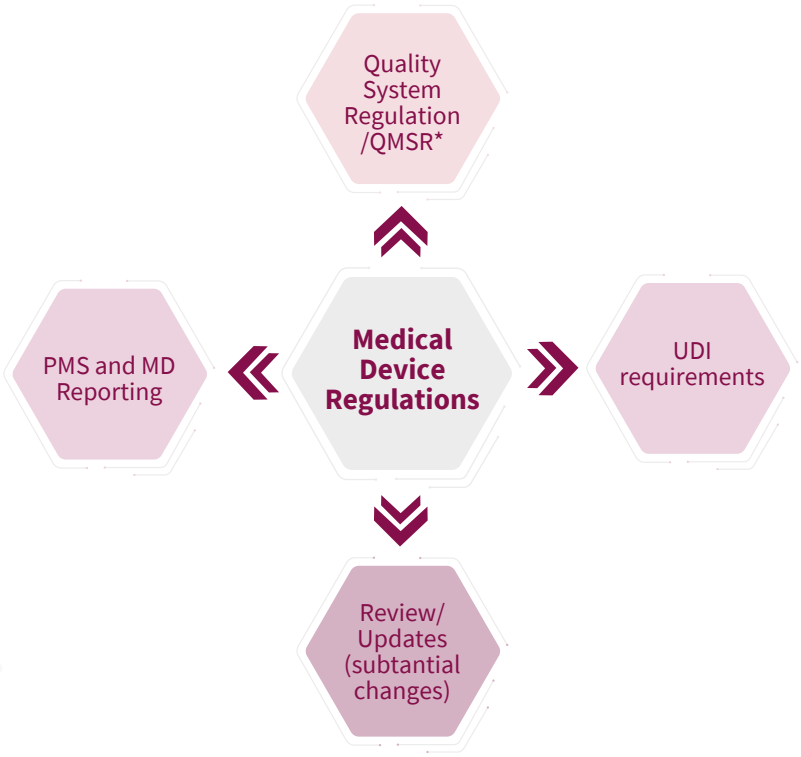
Estimated Review Timeline

The FDA aims to complete the review within 120-150 calendar days, though the timeline may vary depending on device complexity and any additional information (AI) requests. **By law, the FDA must issue a classification determination within 120 days of receiving the request.**

Post-Market and Maintenance

Similar to 510(k) or PMA cleared products, De Novo holders are required to adhere to all relevant medical device regulations, including:

- Good Manufacturing Practices (Quality System Regulation, 21 CFR 820). Note that the FDA has issued the Quality Management System Regulation (QMSR) Final Rule to amend the device current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation, with the rule becoming effective on February 2, 2026, two years after publication.
- Compliance with the Unique Device Identification (UDI) Program.
- Fulfillment of post-market surveillance and Medical Device Reporting (MDR) requirements.
- Review and update of documentation in case of substantial changes in the device or its manufacture.



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How can Asphalion help you?

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MedTech is the specialized division for Medical Device Regulatory Support within Asphalion.

Strategic Guidance
Develop comprehensive roadmaps and prepare De Novo classification requests.

Facilitate FDA Submission Process
Assist in compiling, organizing, and submitting the necessary documentation.

Engage in FDA Meetings
Accompany and represent the client in potential meetings with the FDA, ensuring all communications are effectively managed.

Post-Market Assistance
Provide ongoing support for compliance and regulatory requirements after the product launch.

Multidisciplinary team
Highly qualified personnel

Adaptability and confidentiality

Tailored services

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References to FDA guidelines:

- Guidance document: Acceptance Review for De Novo Classification Requests; Guidance for Industry and Food and Drug Administration Staff; October 2021.
- Guidance document: De Novo Classification Process (Evaluation of Automatic Class III Designation) Guidance for Industry and Food and Drug Administration Staff Document issued on October 5, 2021.

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