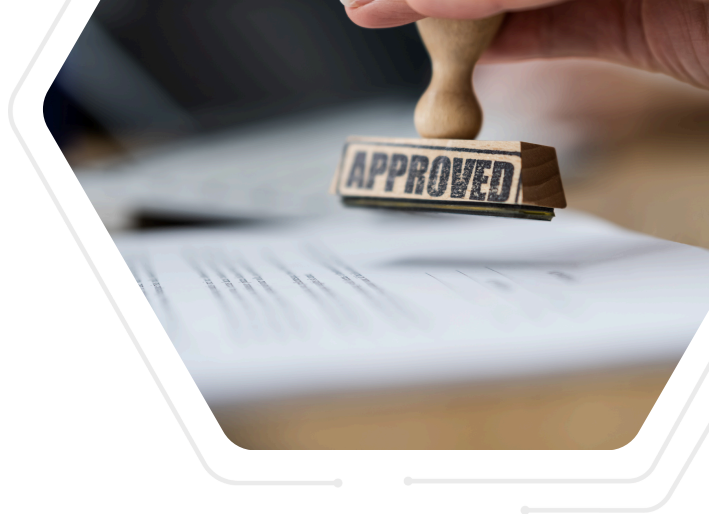




**FDA Authorization procedures
for Medical Devices -
Premarket Approval (PMA)**



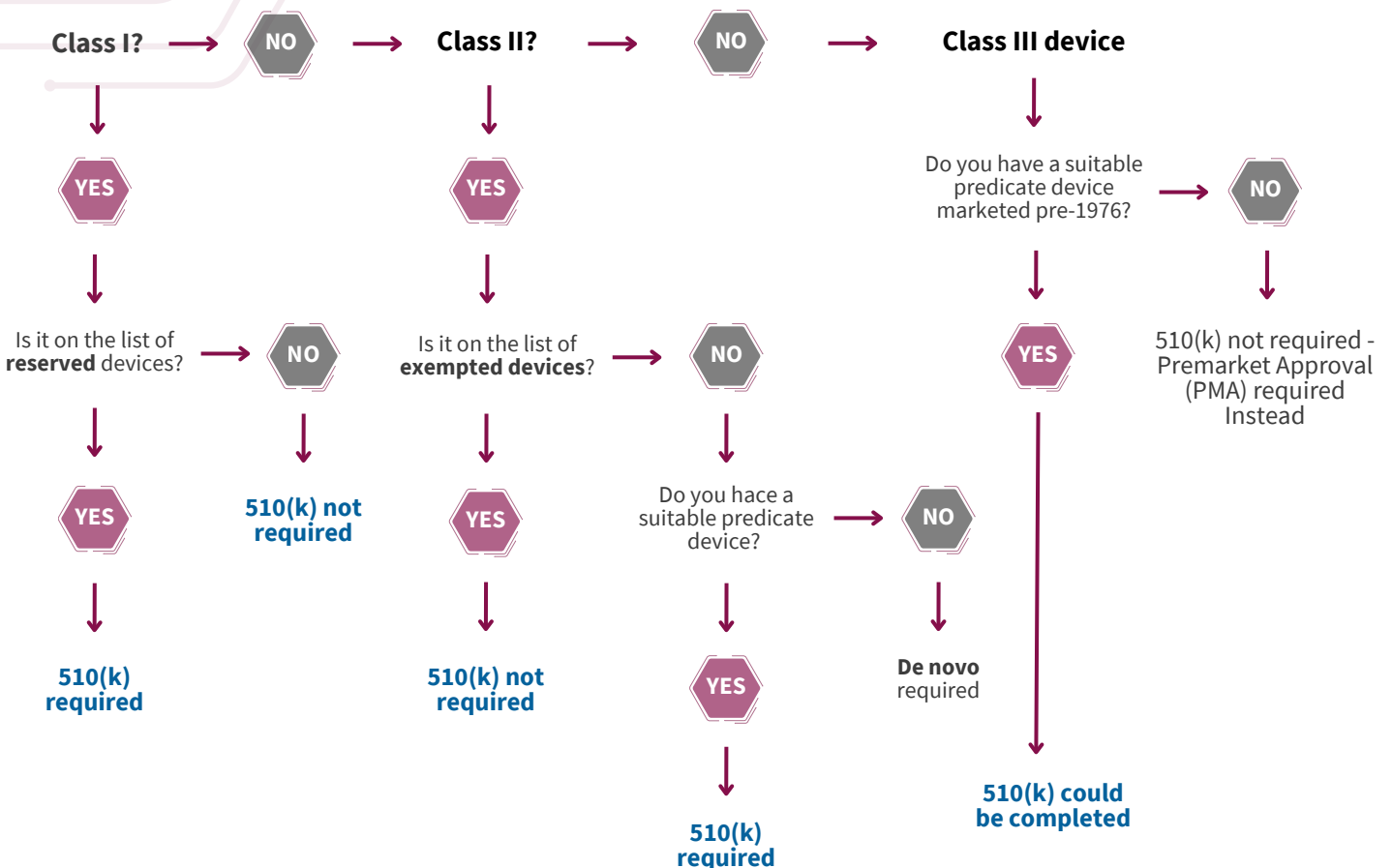
What is PMA?

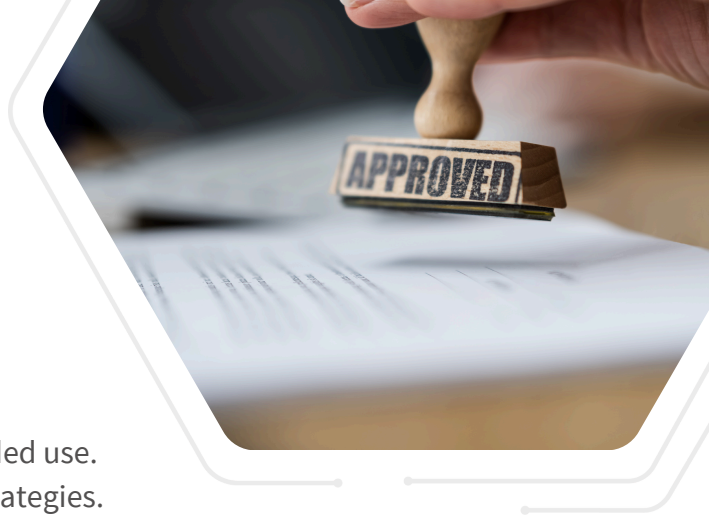
A Premarket Approval (PMA) is the most stringent type of FDA marketing application required for high-risk Class III medical devices. It involves a thorough review of scientific and clinical data to ensure a device's safety and effectiveness before it can be sold in the United States.

When is a PMA required?

- **Class III Devices:** Generally, devices supporting or sustaining human life, posing potential risk of illness or injury.
- **Novel Technologies:** Devices lacking substantial equivalents on the market.
- **Innovative Approaches:** Devices with groundbreaking designs or methods.

Is your device:





Key Steps in the PMA Process

1. Product Definition and Risk Analysis

- Determine the device's classification and intended use.
- Assess potential risks and outline mitigation strategies.

2. Pre-Submission (Q-Sub) activities and meetings

- Engage early with the FDA for feedback on study protocols.
- Clarify data requirements, clinical endpoints, and testing methods.

3. Clinical investigation

- Conduct clinical trials to demonstrate safety and effectiveness.
- Generate robust data with well-defined inclusion/exclusion criteria applicable to the United States' general population.
- Adhere to Good Clinical Practices (GCP) and applicable international guidelines (ISO 14155).

4. PMA Submission

- Compile complete technical documentation, including:
 - Clinical and non-clinical study results.
 - Manufacturing details and process validations.
 - Device labeling, instructions, and warnings.
- Include a comprehensive Quality System, typically under 21 CFR 820 or ISO 13485 alignment.

5. FDA Review

- The FDA conducts an in-depth evaluation of the PMA file.
- Advisory Committee Meetings: For complex or highly innovative devices, external experts may be consulted.
- Inspection of Manufacturing Facilities: FDA may verify compliance with QSR or ISO 13485 standards.

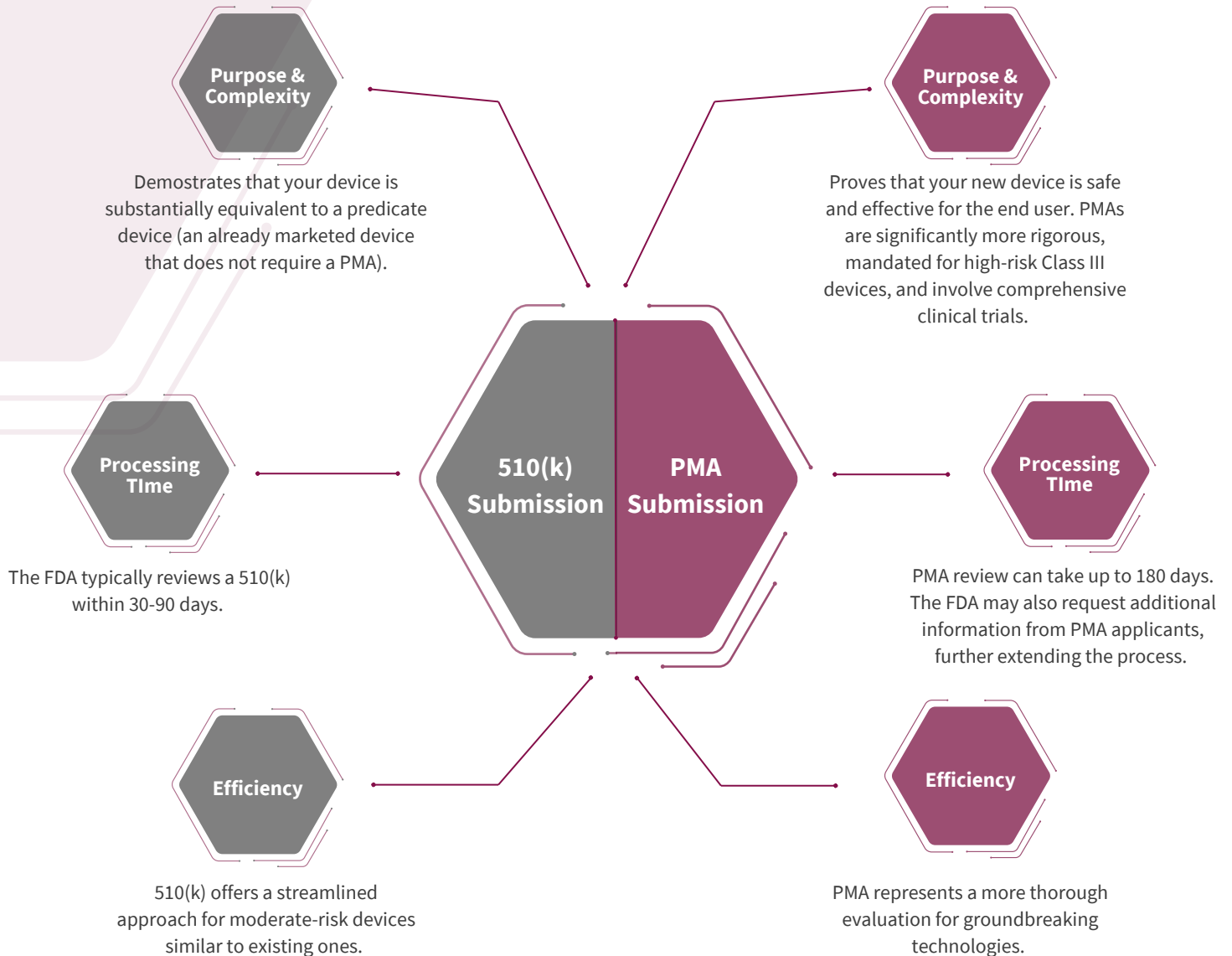
6. Post-Approval Obligations

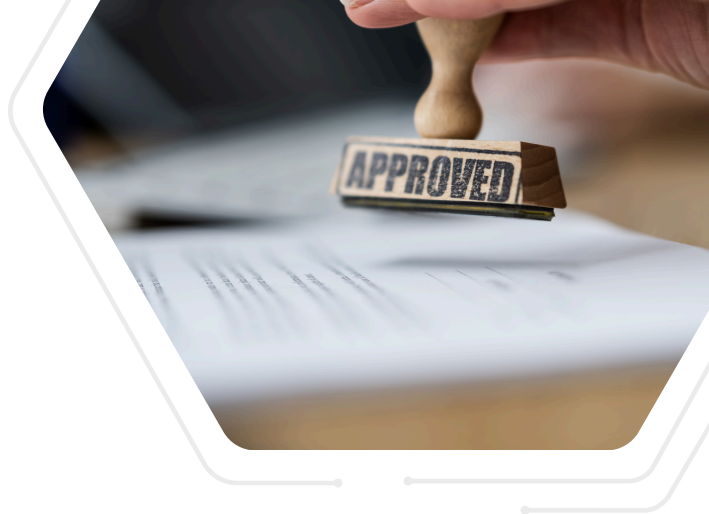
- Post-market Surveillance: Continuous monitoring of device performance and safety.
- Reporting Obligations: Promptly report adverse events and device malfunctions.
- Labeling Updates: Reflect any changes in usage, warnings, or indications.



7. PMA vs. 510(k) and De Novo

- Higher evidentiary standard: PMA requires more extensive clinical data.
- Longer review timelines and costs: Given the substantial evidence required, PMA reviews can take more time than other routes, approximately 180 days. It is also significantly more expensive in regards to FDA fees (\$540,783 for general companies and \$135,196 for small companies as of August 2025).
- Safety and effectiveness: Comprehensive tests, studies, and manufacturing checks.





8. The 4 Types of PMA Submissions

The FDA provides several distinct PMA submission routes, each tailored to different development strategies. Here's a concise look at the four primary pathways:

- **Traditional PMA:** The most extensive option, requiring a full PMA application complete with all the necessary evidence for thorough evaluation.
- **Modular PMA:** Offers a phased approach, enabling sponsors to submit and receive feedback on modular sections of the application in stages.
- **Product Development Protocol (PDP):** Designed for products undergoing ongoing development, allowing incremental submission of evidence as it becomes available.
- **Humanitarian Device Exemption (HDE):** A streamlined mechanism for devices intended to assist individuals with rare conditions, featuring reduced data requirements.

9. Emerging Trends

- **Digital Health:** SaMD or AI-driven solutions can fall under PMA if they are high-risk.
- **Harmonization:** FDA initiatives to align with international standards (e.g., integrating ISO 13485 as in the past months).

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