

FDA Medical Device Regulatory Process

INTRODUCTION & OVERVIEW

The FDA's [Center for Devices and Radiological Health \(CDRH\)](#) oversees the [Total Product Life Cycle](#) for medical devices and is responsible for assuring their safety and effectiveness. Most importantly, CDRH facilitates medical device innovation to provide physicians, patients, and caregivers with timely access to new products.

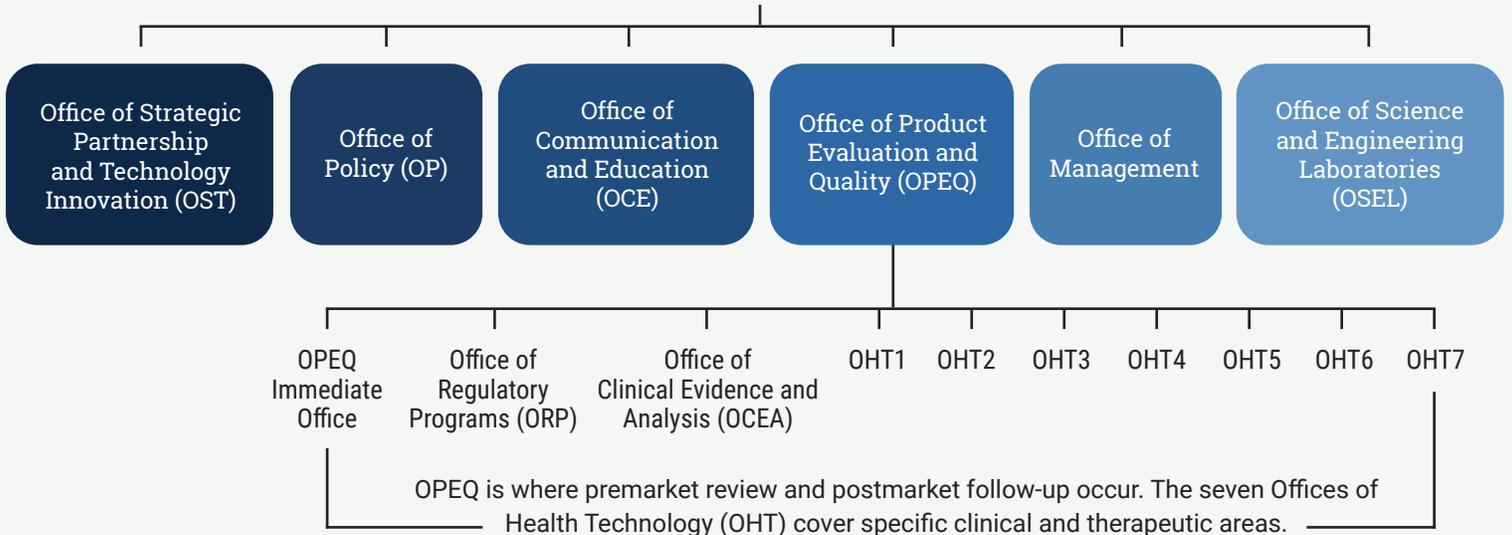
FDA Medical Device User Fee Amendments

[Medical Device User Fee Amendments \(MDUFA\)](#) were created to support the premarket review process and establish FDA performance goals for device review, including clearance or approval. The most recent [MDUFA Commitment Letter](#) can be found on FDA's website. Medical device companies pay user fees to the FDA at the time of their submission. On behalf of the medical technology industry, AdvaMed leads MDUFA negotiations with FDA and monitors its commitment to performance goals.

- STEP 1** Identify medical device classification
- STEP 2** Choose the most appropriate premarket submission based on device classification
- STEP 3** Perform testing to show device safety and effectiveness, including clinical trials if needed (IDE application)
- STEP 4** Prepare a submission (e.g. 510(k), De Novo, Premarket Approval, Humanitarian Device Exemption)
- STEP 5** Send the submission to FDA
- STEP 6** Register facilities and list distributed devices, following FDA clearance or approval
- STEP 7** Adhere to post-market requirements to demonstrate continued safety and effectiveness

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Office of the Center Director (OCD)



PREMARKET

Device Classification

CLASS I:

Most are **exempt** from premarket notification submissions, requiring **only general** controls, which are the basic authorities FDA uses to regulate devices.

CLASS II:

Premarket Notification 510(k): Most Class II devices require 510(k) clearance in which FDA determines whether a product is substantially equivalent to a predicate.

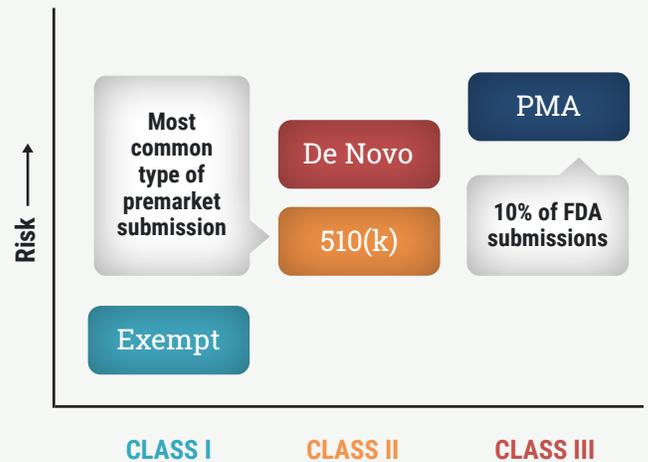
De Novo: De Novo requests allow novel devices to be classified as Class I or Class II without a predicate.

CLASS III:

Premarket Approval (PMA): Almost all Class III devices require a PMA, the most stringent type of premarket submission, requiring extensive clinical trials and performance data.

Investigational Device Exemption (IDE)

Higher risk devices that require clinical trials must submit an IDE, allowing companies to gather data for 510(k)s, PMAs, and other submissions.



Pre-Submission Program

The FDA **Pre-Submission Program** allows medical device companies to obtain FDA feedback before completing a premarket application. Sponsors may request feedback in the form of an in-person meeting, teleconference, or written response.

Breakthrough Devices Program

The **Breakthrough Devices Program** allows innovative medical devices to be built, tested, and approved in a timely manner so that they may be used for diagnosis and/or treatment of life-threatening illnesses. Although the process is interactive and prioritized, companies are still required to follow the same set of regulatory standards as companies whose devices are not included in the program.



Payor Communication Task Force

FDA established the **Payor Communication Task Force** to reduce the amount of time between approval or clearance and coverage decisions, allowing manufacturers and payors to build a working relationship and clarify data requirements in the early stages of product development.

CDRH Learn

FDA launched **CDRH Learn** to provide industry with educational resources pertaining to medical device regulations. The webpage contains learning modules, including videos and slide presentations, that cover both premarket and postmarket topics.

AdvaMed Working Groups

FDA Strategy Working Group

T&R Regulatory Group

Staff Lead: Janet Trunzo, Senior Executive Vice President, Technology and Regulatory Affairs

jtrunzo@advamed.org

POSTMARKET

The FDA has multiple authorities to regulate the use and marketing of medical devices following approval or clearance. If a manufacturer fails to comply with any of these regulations, the Agency may utilize enforcement mechanisms to ensure compliance.

Medical Device Postmarket Surveillance

General Controls

The [Quality System Regulation \(QSR\)](#) requires manufacturers to follow [Good Manufacturing Practices \(GMPs\)](#). The QSR is comprised of the following **Quality Management subsystems**:

- **Design Controls**
- **Material Controls**
- **Corrective and Preventative Actions**
- **Production and Process Controls**
- **Equipment and Facility Controls**
- **Records, Documents, Change Controls**

Manufacturer inspections ensure that facilities are adhering to the FDA's rules and regulations. If manufacturers are not following appropriate QSRs, the Agency may take enforcement action.

Establishment Registration and Listing requires companies to annually register their production and distribution facilities with the FDA. They must also list the devices that they manufacture and distribute.

Additional Requirements

The [Medical Device Reporting \(MDR\)](#) Regulation was implemented for manufacturers, importers, and device user facilities to report device-related safety complaints from health professionals, patients, caregivers, or consumers. **Manufacturers of any device class are required to report adverse events (i.e. serious injury or death) or malfunctions to the FDA.** Facilities that use medical devices must report the annual number of device-related deaths and serious injuries to the FDA. The [Manufacturer and User Facility Device Experience \(MAUDE\)](#) is a public database that contains MDRs submitted to the FDA.

Special controls are necessary when general controls alone are insufficient to assure the safety and effectiveness of Class II devices. They are device-specific and determined based on intended use and risk-benefit profiling.

The FDA may require a manufacturer to **track** their Class II or Class III device if:

1. **failure of the device leads to adverse health consequences,**
2. **the device is implanted in vivo for more than one year, or**
3. **the device is life-sustaining and used outside of its user facility.**

Administrative & Legal Actions

Recalls are usually initiated by the device manufacturer, but the FDA may issue a recall order if it considers a device to be a serious health risk. In some cases, the FDA may require the manufacturer to:

1. **stop distributing its device,**
2. **notify health professionals and user facilities, and**
3. **instruct these professionals and user facilities to stop using its device.**

FDA may issue a **Warning Letter** to a manufacturer if it determines that a company or product is in violation of the Food, Drug, & Cosmetic Act (FDCA). Warning Letters are usually addressed to the company's CEO.

The FDA may take additional administrative and judicial actions for non-compliance, including:

- **Administrative Detentions**
- **Temporary Suspension of Approval**
- **Civil Penalties**
- **Public Health Notifications**
- **Import Detentions**
- **Seizures**
- **Injunctions**
- **Criminal Prosecutions**

Postmarket Policy Roadmap

Medical Device Safety Action Plan

The [FDA's Medical Device Safety Action Plan](#), published in April 2018, is designed to protect patients and to enhance the development of safe, innovative medical devices that address unmet clinical needs.

National Evaluation System for Health Technology (NEST)

In August 2016, the FDA provided initial funding for the establishment of [NEST](#) to generate better evidence for medical device evaluation and regulatory decision-making. While not yet operational, NEST will synthesize real-world evidence from clinical registries, electronic health records, and medical billing claims. Refer to the [Real-World Evidence Guidance Document](#) for more information.

AdvaMed Working Groups

Postmarket Policy Working Group

Staff Lead: Zach Rothstein,

Vice President,

Technology and Regulatory Affairs

zrothstein@advamed.org

Quality System Working Group

Staff Lead: Steve Silverman,

Vice President,

Technology and Regulatory Affairs

ssilverman@advamed.org