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.

Office of the Center Director (OCD)

OPEQ, immediately, Office, of, Regulatory, Programs, Office, of, Communication, and, Analysis, Office, of, Product, Evaluation, and, Quality, Office, of, Management, Office, of, Science, and, Engineering, Laboratories. OPEQ is where premarket review and postmarket follow-up occur. The seven Offices of Health Technology (OHT) cover specific clinical and therapeutic areas.
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.

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.

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.
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.

#### 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.

The 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**

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