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Medical Devices (US Edition)

According to the FDA, **medical devices** may be classified as:

- Low risk (**class I**)
- Moderate risk (**class II**)
- High risk (**class III**)
- Unclassified

All devices must be developed and manufactured in accordance with **general controls** unless exempted by regulations.

General controls are the basic provisions of the May 28, 1976, Medical Device Amendments to the Food, Drug, and Cosmetic Act that provide the FDA with the means of regulating devices to ensure their **safety** and **effectiveness**.

While some class I devices may be exempt from **GMP** (good manufacturing practices) requirements, all class II, III, and unclassified devices must comply with GMP. Some class II devices and all class III devices require **special controls**, which are needed when general controls alone are insufficient to provide reasonable assurance of the safety and effectiveness of the device.

When submitting a marketing application to the FDA, there are four possible routes:

- Exemption
- 510(k)
- De Novo
- PMA (premarket approval)

Only some class III devices require a **PMA**, which is mandatory when those devices are intended to support or sustain human life or prevent impairment of human health.

If a class III device presents a **potential unreasonable risk of illness or injury** for which general controls and special controls are insufficient to provide reasonable **assurance of safety and effectiveness** (or for which there is insufficient information to make such a determination), a PMA will also be mandatory. Additionally, devices that are not within a type marketed before the date of the Medical Device Amendments of 1976 are automatically classified into class III under federal law.

Unless exempted, all medical devices not needing a PMA will require a **510(k)** — a premarket notification submission based on a medical device being **substantially equivalent** to a product already lawfully marketed.

Novel devices may follow the **De Novo** route, which is an alternative to PMA. The De Novo process was designed to review and classify novel devices that do not have a **clear predicate** or do not fall into **existing regulations**. Predicate refers to devices that were legally marketed before 1976, to which future 510(k) submission products must be proven substantially equivalent.

Regarding **clinical trials**, class I devices are exempt. They are mandatory for some class II devices and most class III devices. Most 510(k) applications do not require clinical trials, but most PMA applications do.

More information:

- Center for Devices and Radiological Health. Medical Devices. U.S. Food and Drug Administration. Published 2019. https://www.fda.gov/medical-devices
- Demystifying the FDA. www.youtube.com. Accessed March 9, 2022. https://youtu.be/yfghqN-GfoY
- Regipedia Homepage. regipedia.raps.org. Accessed March 9, 2022. https://regipedia.raps.org