FDA Requirements for Medical Technology

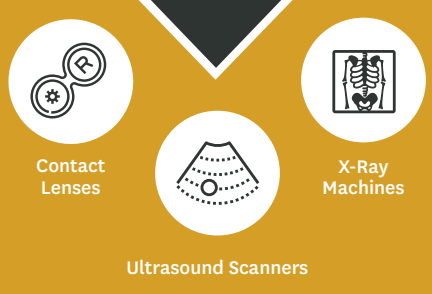
The U.S. Food and Drug Administration (FDA) employs a risk-based approach to regulating medical technology where the level of requirements to determine a device or diagnostic's safety and effectiveness is commensurate to its risk.

Premarket Requirements

Class I
Low Risk

Most exempt from premarket submission requirements

Class II
Moderate Risk



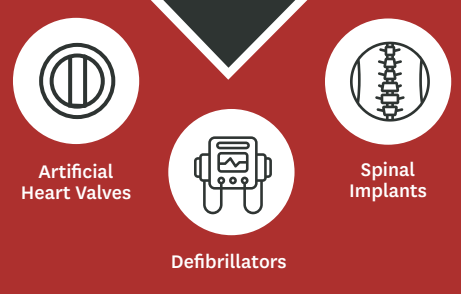
Premarket Clearance 510(k)

Must demonstrate "substantial equivalence" to one or more devices legally marketed in the U.S.

Information in a 510(k) submission includes:

- Bench Testing
- Animal Studies (if deemed necessary by FDA)
- Batteries of non-clinical tests (biocompatibility, shelf-life, shock and vibration, temperature cycling, etc.)
- Tests demonstrating conformance with relevant national and international standards
- Any additional requirements specified by FDA, including clinical studies

Class III
High Risk



Premarket Approval Applications (PMA)

Must establish a "reasonable assurance of safety and effectiveness" as demonstrated by valid scientific evidence.

A complete PMA application will include:

- Results of any clinical studies
- Description of manufacturing & processing
- Description of the device including components, ingredients, properties, and principles of operation
- Full reports of all known information on the device's safety and effectiveness
- Results of non-clinical trials (bench/animal testing)
- Proposed professional and patient labeling
- A summary of safety and effectiveness data

Postmarket Requirements

All manufacturers of medical devices and diagnostics approved or cleared for marketing in the U.S. must comply with the following requirements:

Quality Systems:
Companies must have processes and procedures in place to ensure products are manufactured consistently according to pre-determined specifications for safety and effectiveness.

Registration and Listing:
Facilities involved in the manfacture and distribution of medical devices in the U.S. must register annually with FDA and list the products and activities performed at those facilities.

Medical Device Reporting:
Manufacturers must report to FDA any device-related incidents, deaths, serious injuries, and device malfunctions which are likely to cause or contribute to death or serious injury if they were to occur.

Recalls:
Companies must report to FDA any correction or removal from the market of a medical device intended to reduce a risk to the public health.

Certain Class II and Class III devices can be subject to additional postmarket requirements:

Tracking	Postmarket Surveillance	Condition of Approval Studies
FDA may order manufacturers to adopt a method of tracking for devices whose failure would be reasonably likely to have serious, adverse health consequences; or which is intended to be implanted in the human body for more than one year; or are life-sustaining or life-supporting devices used outside of a device user facility.	FDA can require a manufacturer to conduct a range of activities involving the collections and analysis of data on a marketed device related to anticipated or unforeseen adverse events or other information necessary to protect the public health and safety.	As a condition of marketing approval for a Class III device, FDA can require continuing evaluation and periodic reporting on the safety, effectiveness, and reliability of the device for its intended use.