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: Must demonstrate "substantial equivalence" to one or more devices legally marketed in the U.S.
- **Class III** High Risk: 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.

The FDA can require a manufacturer to conduct a range of activities, including examinations and analyses of clinical data, to anticipate and evaluate adverse effects of the device or dismisses other information necessary to protect the public health and safety.

As a condition of marketing approval for a Class III device, FDA may require continuing evaluation and periodic reporting on the safety, effectiveness, and reliability of the device for its intended use.

**Postmarket 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 manufacture 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.
- Recall: 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.

**FDA Requirements for Medical Technology**

**Premarket Requirements**

- **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:
  - Technical Testing
  - Clinical Studies (if deemed necessary by FDA)
  - Results of non-clinical trials (bench/animal testing)
  - Tests demonstrating conformance with relevant national and international standards
  - Any additional requirements specified by FDA, including clinical studies.

- **Premarket Approval (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
  - Information on the design and manufacturing process
  - Descriptions of the device, including components, intended use, ingredients, properties, and structures of operation
  - Full impacts of all known information on the device safety and effectiveness
  - Results of non-clinical tests (bench and animal testing)
  - Proposed professional and patient labeling
  - A summary of safety and effectiveness data.

**Postmarket Requirements**

- **Tracking:** Companies must maintain a database of adverse events and serious adverse events related to their devices.
- **Postmarket Surveillance:** Companies must conduct surveillance activities to detect, investigate, and follow-up on adverse events and perform postmarket surveillance activities.
- **Condition of Approval Studies:** Companies must conduct studies to evaluate the long-term safety and effectiveness of their devices.

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

- **Batteries of non-clinical tests (biocompatibility, shelf-life, shock and vibration, temperature cycling, etc.)**
- **Tests demonstrating conformance with relevant national and international standards**
- **Full reports of all known information on the device’s safety and effectiveness**
- **Results of non-clinical trials (bench and animal testing)**
- **Proposed professional and patient labeling**
- **A summary of safety and effectiveness data.**

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

- **Examinations:** Certain Class II and Class III devices may be subject to additional postmarket requirements, including performance standards, postmarket surveillance, and clinical studies.

**Registration and Listing:**

- Facilities involved in the manufacture 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.

**Recall:**

- 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.

**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 manufacture 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.

**Recall:**

- 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.