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.

### 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 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 recur.

- **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:**
  - FDA may require a device manufacturer to label a device with a device identifier (UDI) and send the UDIs to designated partners.
  - A UDI includes information such as the device type, size, and serial number, which is intended to improve the ability to trace the device.

- **Postmarket Surveillance:**
  - FDA may require further information to monitor the device's performance in use, including clinical studies, to ensure the device performs as intended.

- **Condition of Approval Studies:**
  - If a medical device is approved based on clinical studies, it must undergo additional studies to verify device safety and effectiveness.

### FDA Requirements for Medical Technology

**Class I – Low Risk**

- **Premarket Requirements:**
  - Most exempt from premarket submission requirements

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

**Class II – Moderate Risk**

- **Premarket Requirements:**
  - Premarket Clearance (510(k))

  - Most demonstrate “substantial equivalence” to one or more devices legally marketed in the U.S.

- **Postmarket Requirements:**
  - Information in a 510(k) submission includes:
    - Bench testing
    - Animal studies (if deemed necessary by FDA)
    - Results of non-clinical tests (biocompatibility, shelf-life, shock and vibration, temperature cycling, etc.)
    - Results of clinical studies
    - Description of manufacturing and processing
    - Description of the device including components, ingredients, properties, and principles of operation
    - Any additional requirements specified by FDA, including clinical studies

- **Premarket Approval Applications (PMA)**
  - Most similar to a research exemption of safety and effectiveness as demonstrated through extensive clinical experience.

  - A complete PMA application will include:
    - Results of any clinical studies
    - Description of manufacturing
    - Description of the device
    - Results of clinical studies
    - Full summary of all known information on the device's safety and effectiveness
    - Results of non-clinical tests
    - Proposed professional and patient labeling
    - A summary of safety and effectiveness data

**Class III – High Risk**

- **Premarket Requirements:**
  - Premarket Approval Applications (PMA)

  - Must establish a “reasonable assurance of safety and effectiveness” as demonstrated by valid scientific evidence

  - Results of any clinical studies

  - Description of manufacturing

  - Description of the device

  - Full reports of all known information on the device's safety and effectiveness

  - Results of non-clinical tests

  - Proposed professional and patient labeling

  - A summary of safety and effectiveness data

- **Postmarket Requirements:**
  - A complete PMA application will include:
    - Results of any clinical studies
    - Description of manufacturing
    - Description of the device
    - Results of clinical studies
    - Full summary of all known information on the device's safety and effectiveness
    - Results of non-clinical tests
    - Proposed professional and patient labeling
    - A summary of safety and effectiveness data

- **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.

- **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 recur.

- **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.

- **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 recur.

- **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.