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

- **Most exempt from premarket submission requirements**
  - Bathtubs
  - Blood glucose meters
  - Examination gloves
  - Non-aspirin pain relievers
  - Oral contraceptives
  - Pyrometers
  - Thermometers
  - Ultrasound scanners
  - X-ray machines
  - Artificial heart valves
  - Defibrillators
  - Spinal implants

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

- **Contact Lenses**

- **Premarket Clearance 510(k)**
  - Must demonstrate “substantial equivalence” to a device or devices legally marketed in the U.S.
  - Information in a 510(k) submission includes:
    - Device Testing
    - Animal Studies (if deemed necessary by FDA)
    - Results of non-clinical trials (bench/animal testing)
    - Description of the device including components, ingredients, properties, and principles of operation
    - Proposed professional and patient labeling
    - 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

- **Premarket Approval Applications (PMA)**
  - Must establish “reasonable assurance of safety and effectiveness” as demonstrated by valid scientific evidence.
  - A complete PMA application will include:
    - Results of any clinical studies
    - Descriptions of manufacturing & processing
    - 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
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### 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 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.

### FDA Requirements for Medical Technology

- **Class I** Low Risk
  - Low or no risk of injury
  - Most devices fall into this category

- **Class II** Moderate Risk
  - Class II devices may be subject to additional postmarket requirements
  - Certain Class II and Class III devices can be subject to additional postmarket requirements

- **Class III** High Risk
  - Most devices fall under this category
  - High risk of injury

- **Preliminary Data**
  - Results of any clinical studies
  - Descriptions of manufacturing & processing
  - 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

- **Medical Device Reporting:**
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- **FDA Requirements for Medical Technology:**
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- **Certain Class II and Class III devices can be subject to additional postmarket requirements:**
  - As a condition of marketing approval for a Class II device, FDA may order manufacturers of a Class II device 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.

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