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

- Most exempt from premarket submission requirements
- Must demonstrate “substantial equivalence” to one or more devices legally marketed in the U.S.

Bandages
- Examination Gloves
- Manual Wheelchairs
- Contact Lenses
- Ultrasound Scanners
- X-Ray Machines
- Artificial Heart Valves
- Defibrillators
- Spinal Implants

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 tracking and surveillance to collect information on the device’s performance and effectiveness.

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.

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.

- 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.

Class I - Low Risk
- Most exempt from premarket submission requirements
- Most premarket clearance applications (510(k)) submitted are for Class I devices.

Class II - Moderate Risk
- Submit premarket notification (510(k)) that the device is substantially equivalent to a device legally marketed prior to 1976.
- Submit premarket approval application (PMA) if the device is not substantially equivalent to a legally marketed device or if the device is a new type of device.

Class III - High Risk
- Device is a “reasonable assurance of safety and effectiveness” as demonstrated by valid scientific evidence
- A complete PMA application will include:
  - Results of any clinical studies
  - Design history files
  - Design files
  - Design reports
  - Demonstration of the device’s performance including known malfunctions and failures
  - Premarket clinical data
  - Postmarket surveillance data

Postmarket Requirements

- A complete PMA application will include:
  - Results of any clinical studies
  - Design files
  - Design of the device
  - Demonstration of the device’s performance including known malfunctions and failures
  - Premarket clinical data
  - Postmarket surveillance data

- A summary of safety and effectiveness data

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

FDA may order a manufacturer to design a study to evaluate the safety and effectiveness of a device before or after approval.

- Tracking: FDA may require a manufacturer to conduct tracking and surveillance to collect information on the device’s performance and effectiveness.

- Postmarket Surveillance: FDA can require a manufacturer to conduct postmarket surveillance to collect information on the device’s performance and effectiveness.

- Condition of Approval Studies: FDA may require a manufacturer to conduct additional studies after market approval to determine the device’s effectiveness for its intended use.

Information in a 510(k) submission includes:

- Bench testing
- Animal studies (if deemed necessary by FDA)
- Results of non-clinical tests (i.e., bench testing, animal studies, bench testing of materials, etc.)
- Results of clinical studies (i.e., clinical testing, clinical evaluation, etc.)
- Final device specifications and test methods
- Postmarket surveillance data

- Registration and listing of facilities involved in the manufacture and distribution of medical devices
- Medical device reporting to FDA of 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

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