MEDICAL DEVICE REGULATION

CLASSIFICATION OF MEDICAL DEVICES

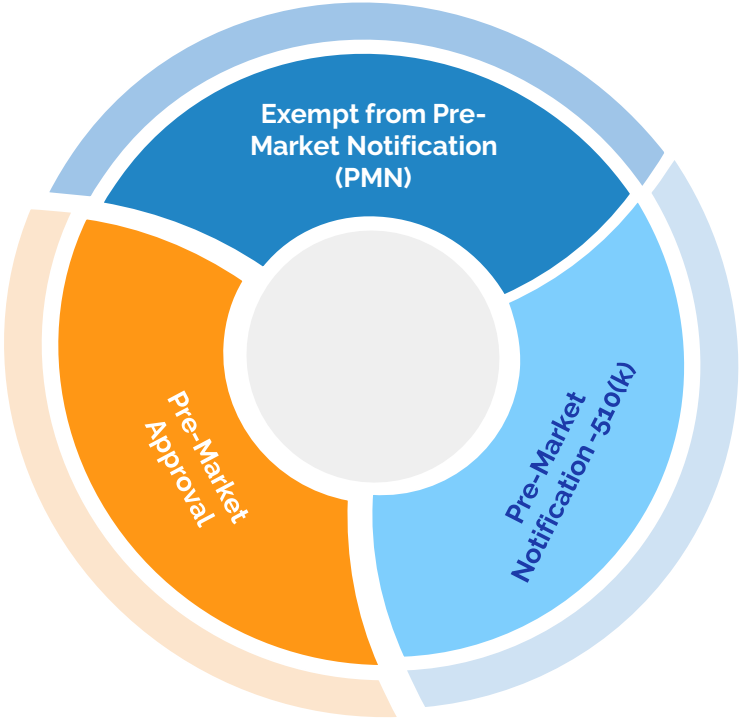
Medical device classification system *is used to* ***assess potential risks*** *associated with the medical device and to* ***decide the regulatory pathway*** *to ensure quality standards are met.*

Device Classifications

Class I	Class II	Class III
General controls applicable.	General and special controls applicable.	General controls applicable.
Low risk medical devices.	Moderate risk medical devices.	Pre-Market Approval (PMA) required.
		High risk medical devices.
		Clinical trials needed.

REGULATORY REQUIREMENTS

FDA Regulatory Pathways



Regulatory Paths

	Exempt from PMN	510(k)	PMA
Class I	✓	✓	
Class II	✓	✓	
Class III			✓

Class I Medical Devices

- Most class I devices are exempt from pre-market notification.

  e.g.: Elastic bandage, dental protector

- Some class I devices need 510(k).

  e.g.: latex patient examination glove, shunt connector

Class II Medical Devices

- Pre-market notification 510(k) required.

  e.g.: Surgical face mask, short term spinal needle

- Some class II devices are exempt from 510(k).

  e.g.: Oscillometer, ECG electrode

Class III Medical Devices

- PMA is required for class III devices.

  e.g.: Pulmonary valve, high frequency ventilator

- To prove safety and effectiveness of the device:

  - Clinical data needed
  - Non-clinical testing required

MARKETING MEDICAL DEVICES IN U.S.A

Establishment registration

- Manufacturer's of medical devices are required to register their establishment with FDA annually.

Device listing

- The generic name or classification name of the medical device must be listed.

Marketing 510(k) Exempt Devices

- Establishment registration and device listing required.
- Regulatory requirements to be fulfilled:
  - GMP's (unless exempted)
  - Labeling
  - Corrections and removals

Marketing 510(k) Devices

The following requirements should be met:

- Submission of pre-market notification application
- 510(k) clearance
- Establishment registration & device listing

GOOD MANUFACTURING PRACTICE (GMP)

What is GMP?

- Quality system regulations for medical devices are based on Good Manufacturing Practices.

- GMP is outlined in **21 CFR Part 820**.

Quality System Regulations

- 21 CFR Part 820 establishes:

  - The quality system requirements

  - Quality procedures like

    - Design controls
    - CAPA process
    - Quality assurance
    - Quality control activities
    - Document controls

What is GMP Exempt?

- Some class I and class II devices are exempt from medical device GMP's.
- The general requirements concerning records and compliant files must be fulfilled.
- For example, elastic bandage, cast bandage etc. are exempt from GMP.

Enquries to

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