

# Device Classification and Reclassification

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# **Preamendment vs. Postamendment Devices**

**The Act divided the arena of medical devices into either:**

- Preamendment Devices or**
- Postamendment Devices**

**Depending on when the devices were introduced into commercial distribution**

# Classification of Preamendment Devices

**Preamendment Devices are classified after FDA has:**

- **Received a recommendation from a device Classification Panel**
- **Published the Panel's recommendation for comment, along with a PR classifying the device; and**
- **Published a FR classifying the device**



# Reclassification of Preamendment Devices

**FDA may reclassify a preamendments device:**

- in a proceeding that parallels the initial classification proceeding**
- based upon “new information” developed as a result of reevaluation of data before FDA originally classified or not presented, available, or developed at that time**



# Classification of Postamendment Devices

- **Postamendment devices are automatically classified into Class III**
- **Those devices remain in Class III and require premarket approval, unless and until**
  - **the device is reclassified into Class I or II**
  - **FDA issues a SE determination**



# Reclassification of Postamendment Devices

- **May be initiated by either FDA or Industry**
- **FDA may, for good cause shown, refer the petition to a device classification panel**
- **the Panel shall make a recommendation to FDA respecting the petition**



# Device Classes

**A device should be placed in the lowest class whose level of control will provide reasonable assurance of safety and effectiveness**

**Class I - General Controls**

**Class II - Special Controls**

**Class III - Premarket Approval**

# Description of Classes

**Class I - devices for which any combination of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of devices**

**General controls include:**

- **prohibition against adulterated or misbranded devices**
- **premarket notification (if reserved)**

# Description of Classes (continued)

- **banned devices**
- **GMPs**
- **registration of manufacturing facilities**
- **listing of device types**
- **record keeping**
- **repair, replacement, refund**

# **Description of Classes (continued)**

## **Class II**

- 1. Devices which cannot be classified into Class I because general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of such device, but**
- 2. For which there is sufficient information to establish special controls to provide such assurance**



# Description of Classes (continued)

## **Special Controls include**

- **Performance Standards (discretionary, voluntary national or international standards, or ones recognized by rulemaking)**
- **Postmarket Surveillance (required or discretionary)**

# Description of Classes (continued)

- **patient registries**
- **development and dissemination of guidelines/guidances**
- **design controls**
- **recommendations and other appropriate actions**
- **tracking requirements**



# Description of Classes (continued)

## **Class III**

- 1. Devices for which insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of the S&E of such device, and**



# **Description of Classes (continued)**

## **2. Such devices are**

- implants (unless general or special controls can mitigate the risks)**
- life sustaining and/or life supporting**
- substantial importance in preventing impairment of human health; or**
- present potential or unreasonable risk of illness or injury**