



Device Reclassification



What is the purpose of this panel meeting?

To provide input to FDA on whether sufficient scientific evidence exists to reclassify a preamendments device type from Class III to Class II



What is a Preamendments Device?

A device of a type that was introduced into interstate commerce prior to May 28, 1976 (the enactment date of the Medical Device Amendments)

How are Preamendments Devices Classified?

FDA:

1. Receives a recommendation from a device Classification Panel
2. Published the Panel's recommendation for comment, along with a Proposed Rule classifying the device; and
3. Published a Final Rule classifying the device
 - If device is classified into Class III, FDA also calls for premarket approval applications (PMAs)

What are the Device Classes?

- Classified based on controls necessary:
 - Class I - General Controls
 - Class II - General and Special Controls
 - Class III - Premarket Approval
- A device should be placed in the lowest class whose level of control provides reasonable assurance of safety and effectiveness

What are Class I Devices?

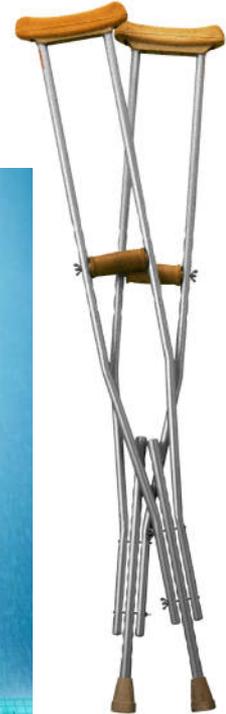
- Devices for which general controls are sufficient to provide reasonable assurance of the safety and effectiveness
- Class I devices typically require no FDA premarket review prior to being marketed

What are General Controls?

- General Controls Include:
 - Prohibition against adulterated or misbranded devices,
 - Good Manufacturing Practices (GMPs),
 - Registration of manufacturing facilities,
 - Listing of device types,
 - Recordkeeping, etc.

What are Some Examples of Class I Devices?

- Adhesive Bandages
- Manual Stethoscope
- Patient Scale
- Exam Light
- Crutches



What are Class II Devices?

- Cannot be classified into Class I:
 - because general controls are insufficient to provide reasonable assurance of the safety and effectiveness of such device, and
 - for which there is sufficient information to establish special controls to provide such assurance
- Class II devices typically require premarket notification to FDA (i.e., a 510(k)) prior to being marketed

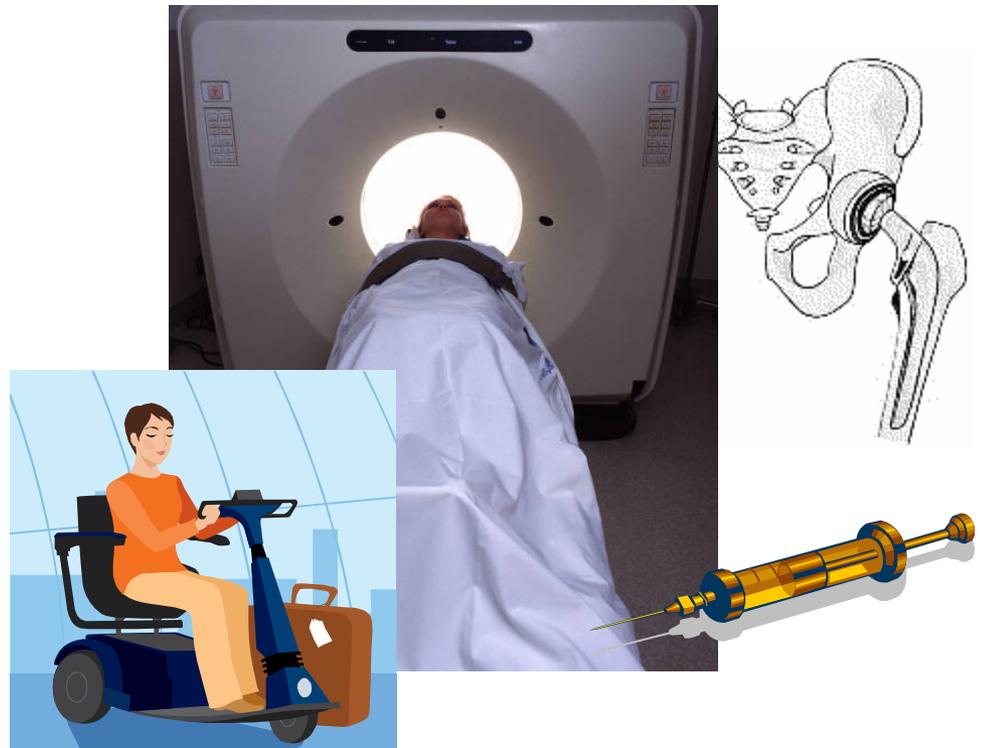
What are Special Controls?

Special Controls include:

- Performance standards,
- Postmarket surveillance,
- Patient registries,
- Development and dissemination of guidance documents, etc.

What are Some Examples of Class II Devices?

- Ventilator
- Echocardiograph (ECG)
- Endoscope
- Hemodialysis System
- Surgical Sutures
- Syringes
- Infusion Pump
- Condom
- Hip Prosthesis
- Powered Wheelchairs
- Computed Tomography (CT) Machines



How are Special Controls Used?

- As an example, for surgical sutures, FDA has issued a special controls guidance to mitigate risks to health:
 - Biocompatibility testing
 - Sterility testing
 - Conformance to the USP monograph
 - Resorption profile testing (for absorbable sutures)
 - Labeling (warnings, precautions, adverse reactions, etc.)
- These special controls, in combination with the general controls, provide reasonable assurance of safety and effectiveness
- Companies must provide evidence in their 510(k) submissions of how the special controls were addressed

What are Class III Devices?

- Cannot be classified into Class II because:
 - insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of the safety and effectiveness, and
 - The devices are:
 - life sustaining and/or life supporting, or
 - of substantial importance in preventing impairment of human health; or
 - presents potential or unreasonable risk of illness or injury
- Class III devices require premarket approval (PMA) prior to being marketed

What are Some Examples of Class III Devices?

- Implantable Pacemakers
- Replacement Heart Valves
- Implantable Spinal Cord Stimulators
- Contraceptive Intrauterine Devices (IUDs)
- Extended Wear Soft Contact Lenses

What are “Class III 510(k)” Devices?

- Preamendments devices where FDA issued a proposed rule classifying them as Class III; however:
 - No final rule was issued, or,
 - A final rule was issued for Class III, but the rule did not contain a date by which companies were required to submit a PMA
- Therefore, these Class III devices are allowed to proceed to market via the 510(k) process until such time as the classification steps are completed.

What is the reclassification process?

- FDA may reclassify a preamendment device:
 - in a proceeding that parallels the initial classification proceeding
 - based upon new information respecting a device either on FDA's own initiative or upon the petition of an interested person

What will happen after this panel meeting?

- FDA will consider the available evidence, including the input of the panel,
- FDA will issue a final rule classifying the device into either Class II or Class III
 - If Class II, existing devices will be subject to any identified special controls and may continue to market
 - If Class III, existing devices will remain on the market, but must receive an approved PMA by a specified time to continue marketing
 - If no PMA is approved, devices will be considered misbranded and must be removed from distribution