



Device Reclassification

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*Implanted Blood Access Devices for
Hemodialysis and Sorbent
Hemoperfusion Devices*

What Is the Purpose of This Panel Meeting?

To provide input to FDA on the classification of preamendments device types and whether FDA should call for PMAs or reclassify to Class II or Class I

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)

What Is the Classification Process?

Recent legislation (FDASIA) has affected the classification of medical devices (including Class III 510(k)s) and FDA must now:

- Publish a proposed order announcing our proposed classification and seek public comment
- Hold a panel meeting if classifying or reclassifying a device type
- Consider comments and all available information, including panel recommendations, prior to issuing a final order finalizing the classification of the device type

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 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 Special Controls?

Special Controls include:

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

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 Class I Devices? (cont)

- Devices which cannot be classified into Class III:
 - Because they are not life sustaining, life supporting, of substantial importance in preventing impairment of public health, and
 - Because they do not present a potential unreasonable risk of illness or injury
- Devices which cannot be classified into Class II:
 - Because insufficient information exists to establish special controls to provide a reasonable assurance of safety and effectiveness

What Are Some Examples of Class I Devices?

- General manual gastroenterology-urology surgical instruments
- Enema kits
- Ostomy pouches
- Protective garments for incontinence

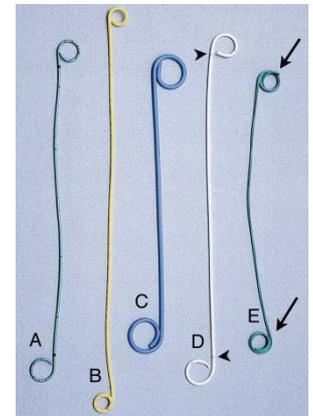


What Are Class II Devices?

- 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 Some Examples of Class II Devices?

- Hemodialyzers
- Lithotripters
- Ureteral stents
- Peritoneal dialysis systems
- Gastrointestinal feeding tubes



How Are Special Controls Used?

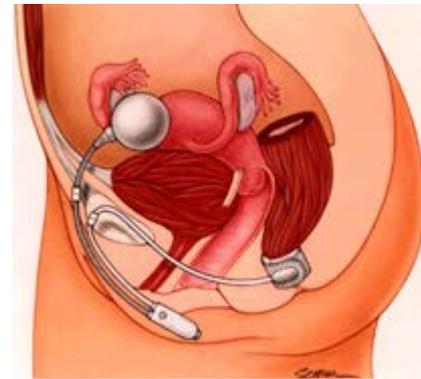
- As an example, percutaneous transluminal coronary angioplasty (PTCA) catheters were reclassified from Class III to Class II (special controls)
- FDA issued a special controls guidance to mitigate risks to health:
 - Biocompatibility testing
 - Performance testing
 - Animal testing
 - Clinical information
 - Sterilization and shelf life
 - Labeling (warnings, precautions, adverse effects, 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 unreasonable risk of illness or injury
- Class III devices typically require premarket approval (PMA) prior to being marketed

What Are Some Examples of Class III Devices?

- Implanted urinary and fecal incontinence devices
- Injectable bulking agents for gastro-urology use
- Intra-gastric implants for morbid obesity
- Extracorporeal photopheresis systems

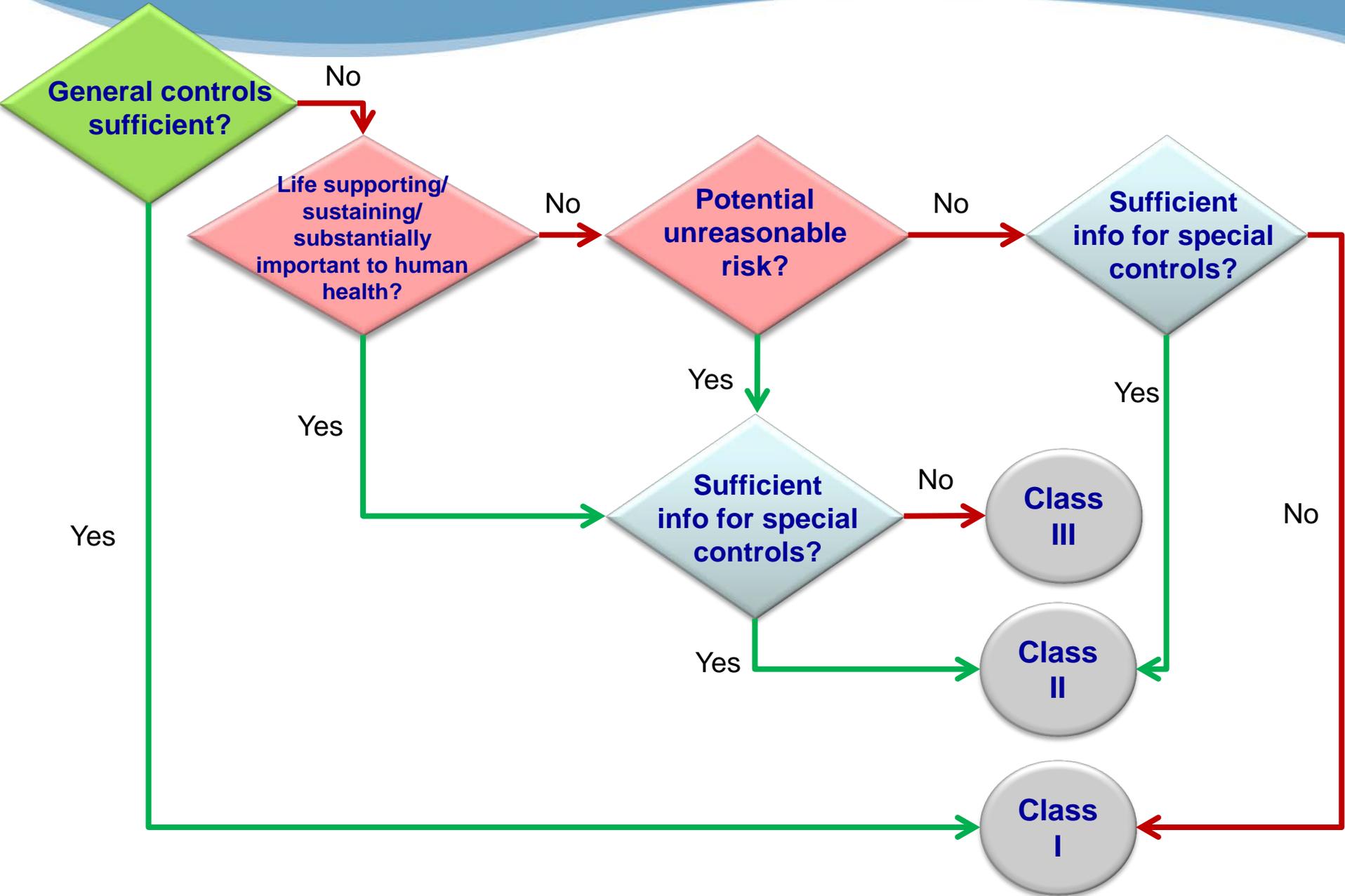


What Are “Class III 510(k)” Devices?

- 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 either a call for PMAs or a reclassification is finalized

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
 - the Agency classifies or reclassifies intended uses which have actually been reviewed by the Agency



What We Need from the Panel

- Input on classification of the device(s) that are the subject of the Panel session
- Input should include:
 - An identification of the risks to health (if any) presented by the device
 - Whether the device is life-supporting/life-sustaining, of substantial importance in preventing impairment to human health, or presents a potential unreasonable risk of illness or injury
 - Whether sufficient information exists to develop special controls
 - Identification of special controls

What Will Happen After This Panel Meeting?

- FDA has issued a proposed order, proposing classification of the device and seeking public comment on the proposal
 - FDA has proposed that, based on the device type, be either reclassified or split the classification based on indications
- FDA will consider the available evidence, including the input of this panel and the public comments
- FDA will issue a final order identifying the appropriate class
 - If Class II, devices may continue to be marketed
 - If Class III, existing devices will remain on the market, but must submit a PMA by a specified time to continue marketing
 - If PMA is not approved, devices will be considered misbranded and must be removed from distribution