Device Classification

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General and Plastic Surgery Devices Panel Meeting

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What Is the Purpose of This Panel Meeting?

For ten pre-amendments, unclassified device types, you will be asked to provide input to FDA on the classification for each one: Class III, Class II, or Class I.

What Are the Device Classes?

- Classified based on controls necessary:
  - Class I (general controls)
  - Class II (special controls)
  - Class III (premarket approval)

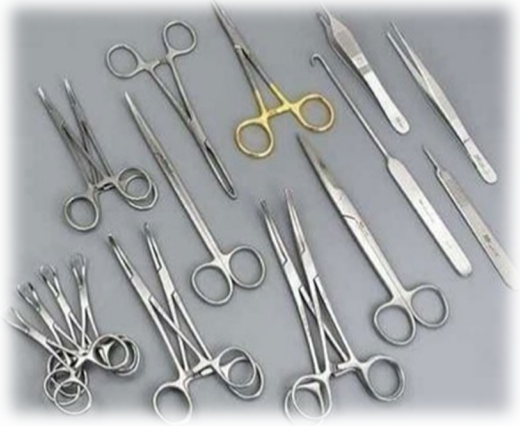
A device should be placed in the lowest class whose level of control provides reasonable assurance of safety and effectiveness.

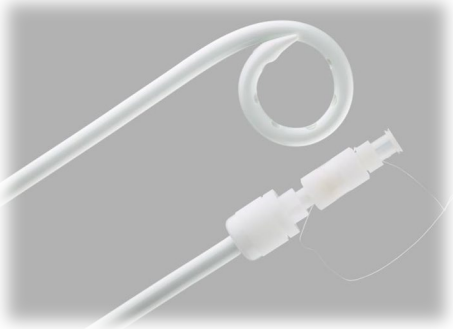
Class I Devices

- Devices for which general controls are sufficient to provide reasonable assurance of the safety and effectiveness

- General controls include:
  - Registration and listing
  - Good manufacturing practices
  - Records and reports
  - Prohibitions against misbranding and adulteration

- Class I devices typically do not require FDA premarket review prior to being marketed



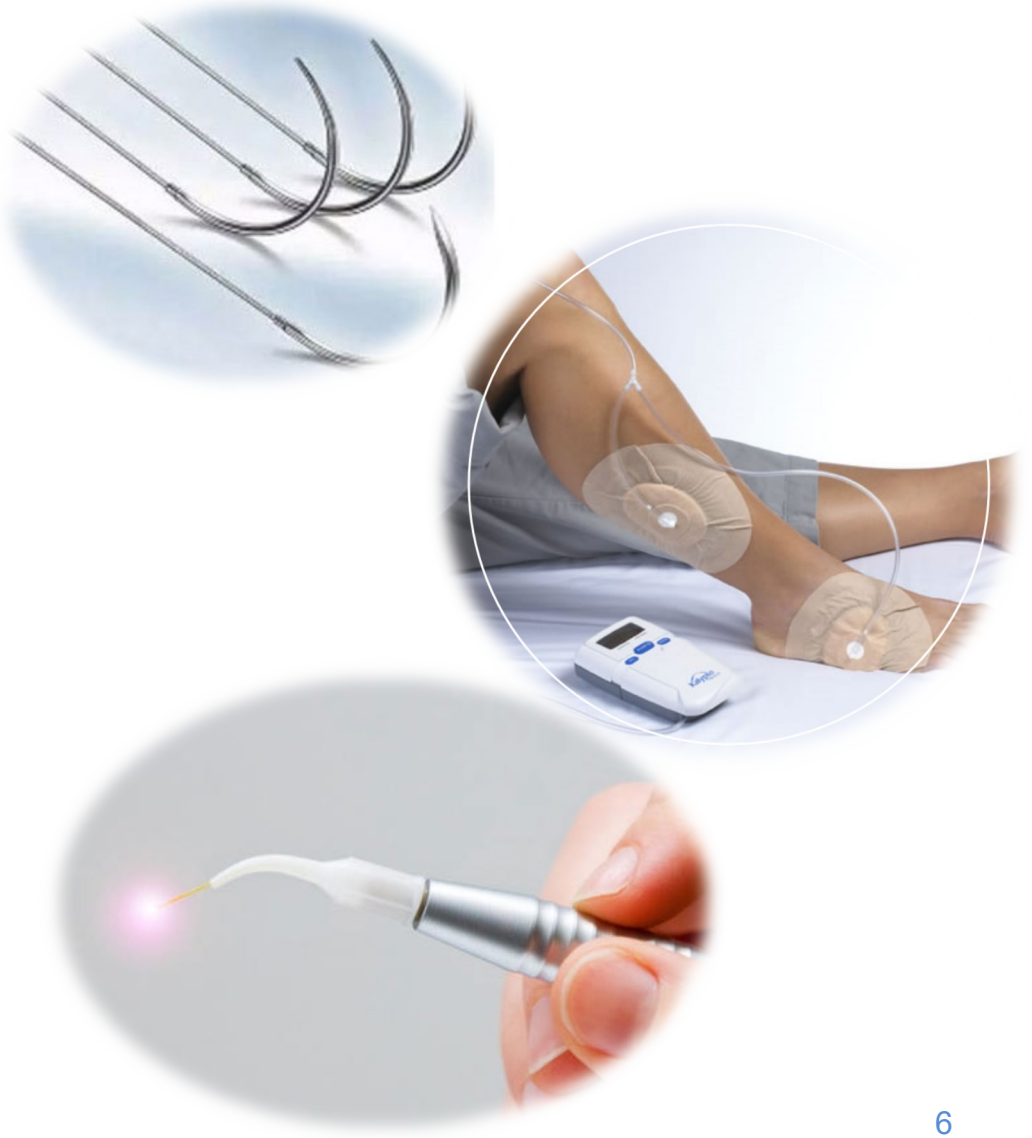


Class I Devices

- Devices which cannot be classified into Class III:
  - Because they are not life-sustaining, life-supporting, of substantial importance in preventing impairment of human 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

Class II Devices

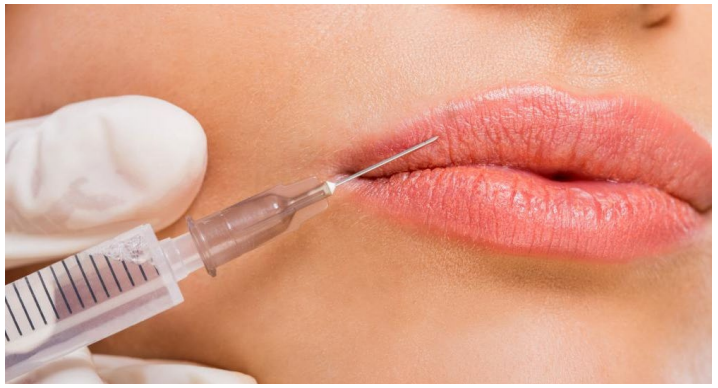
- Cannot be classified into Class I:
  - because general controls are insufficient to provide reasonable assurance of the safety and effectiveness, and
  - for which there is sufficient information to establish special controls to provide such assurance
- Special controls can include:
  - Performance testing
  - Sterilization validation
  - Device-specific labeling requirements
- These special controls, in combination with the general controls, provide reasonable assurance of safety and effectiveness



Class II Devices

- Class II devices typically require premarket notification to FDA (i.e., a 510(k)) prior to being marketed

- Companies must provide evidence in their 510(k) submissions of how the special controls were addressed

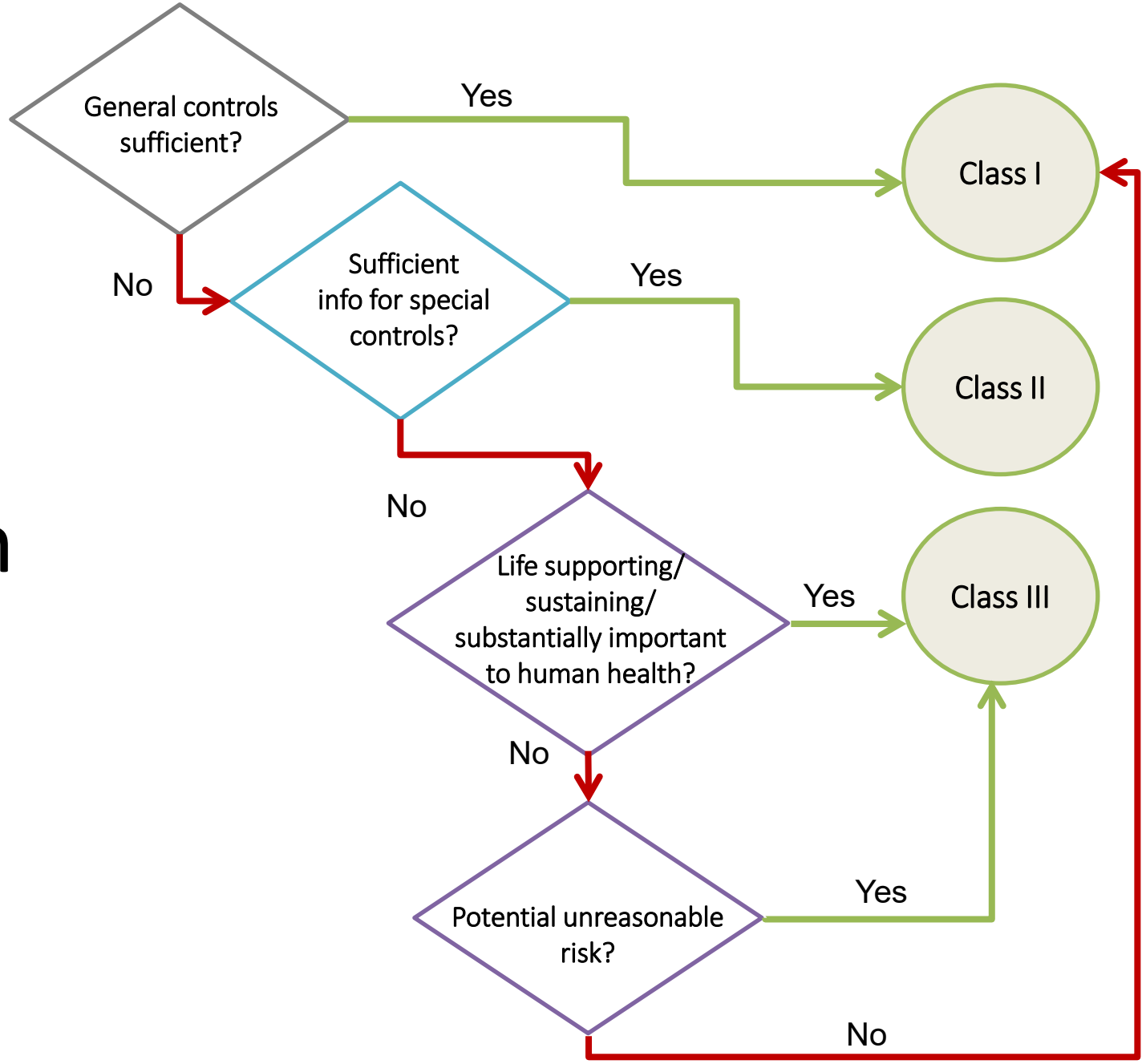


Class III Devices

- Cannot be classified into Class II because:
  - insufficient information exists to determine that general and specials controls are sufficient to provide reasonable assurance of the safety and effectiveness, and
  - The devices:
    - are life-sustaining or life-supporting, or
    - are of substantial importance in preventing impairment of human health; or
    - present a potential unreasonable risk of illness or injury

- Class III devices typically require premarket approval (PMA) prior to being marketed

Device Classification Flowchart



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What Is a Preamendments Device?

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

What Is an Unclassified Device?

A preamendments device that was not classified by the original classification panels; therefore, no classification regulation currently exists for this device type.

What Is the Classification Process for Preamendments, Unclassified Devices?

- Preamendments devices are classified after FDA has:
  - Received a recommendation from a device classification panel
  - Published the Panel's recommendation for comment, along with a proposed rule which proposes classification of the device; and
  - Published a final rule classifying the device

What We Need from the Panel

Input on classification of the device types

- Class III, Class II, or Class I

Input should include:

- Identification of the risks to health presented by each device type
- Whether the device is life-supporting/life-sustaining, of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury
- Whether general controls alone are sufficient
- Whether sufficient information exists to develop special controls
- Identification of special controls

What Will Happen After This Panel Meeting?

Evidence

FDA will consider the available evidence, including the input of this panel and the public comments

Proposed Rule

FDA will issue a proposed rule, proposing classification of the device and seeking public comment on the proposal

Final Rule

FDA will issue a final rule identifying the appropriate class

- If Class I or Class II, devices may continue to be marketed
- If Class III, FDA will issue a separate call for PMAs
  - Existing devices may remain on the market until submission of a PMA by specified date to continue marketing
  - If PMA is not approved, devices would be considered misbranded and must be removed from distribution


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