Device Classification

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Orthopaedic and Rehabilitation Devices Panel Meeting

September 8, 2020

What Is the Purpose of This Panel Meeting?

Part 1: Discuss the available scientific evidence regarding non-invasive bone growth stimulator devices, which are currently regulated as Class III devices. You will be asked to recommend whether they should remain in Class III, or be reclassified to Class II.

Part 2: For four preamendments, 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

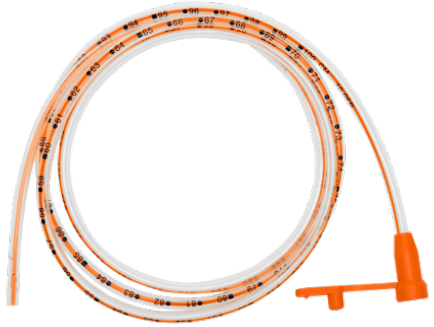
- Class I devices typically do not require FDA premarket review prior to being marketed

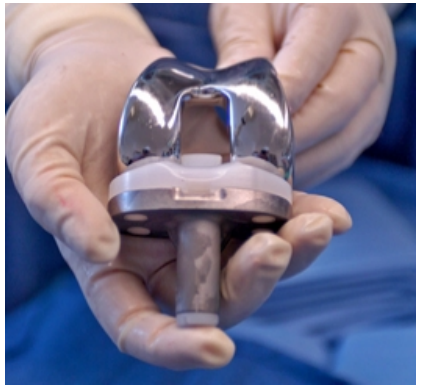
Class I Devices

- 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

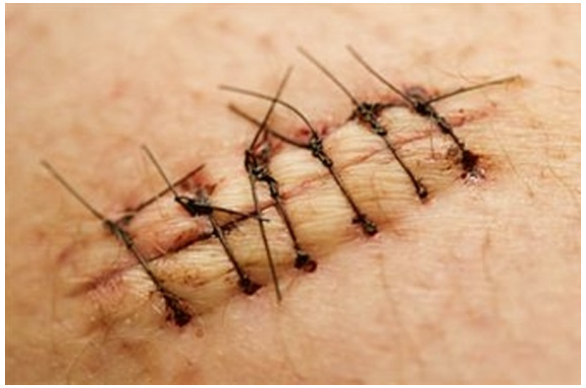
Class II Devices

- 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

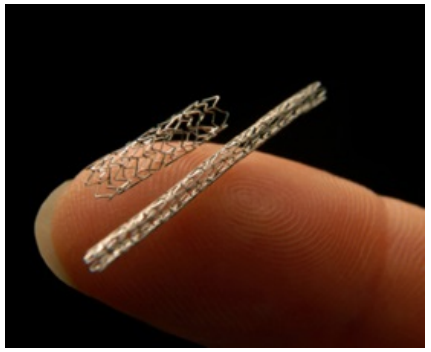
Class II Devices

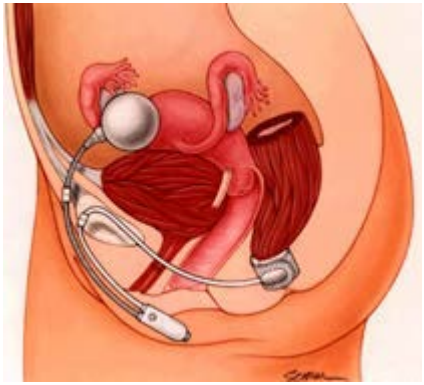
- Class II devices typically require premarket notification to FDA (i.e., a 510(k)) prior to being marketed

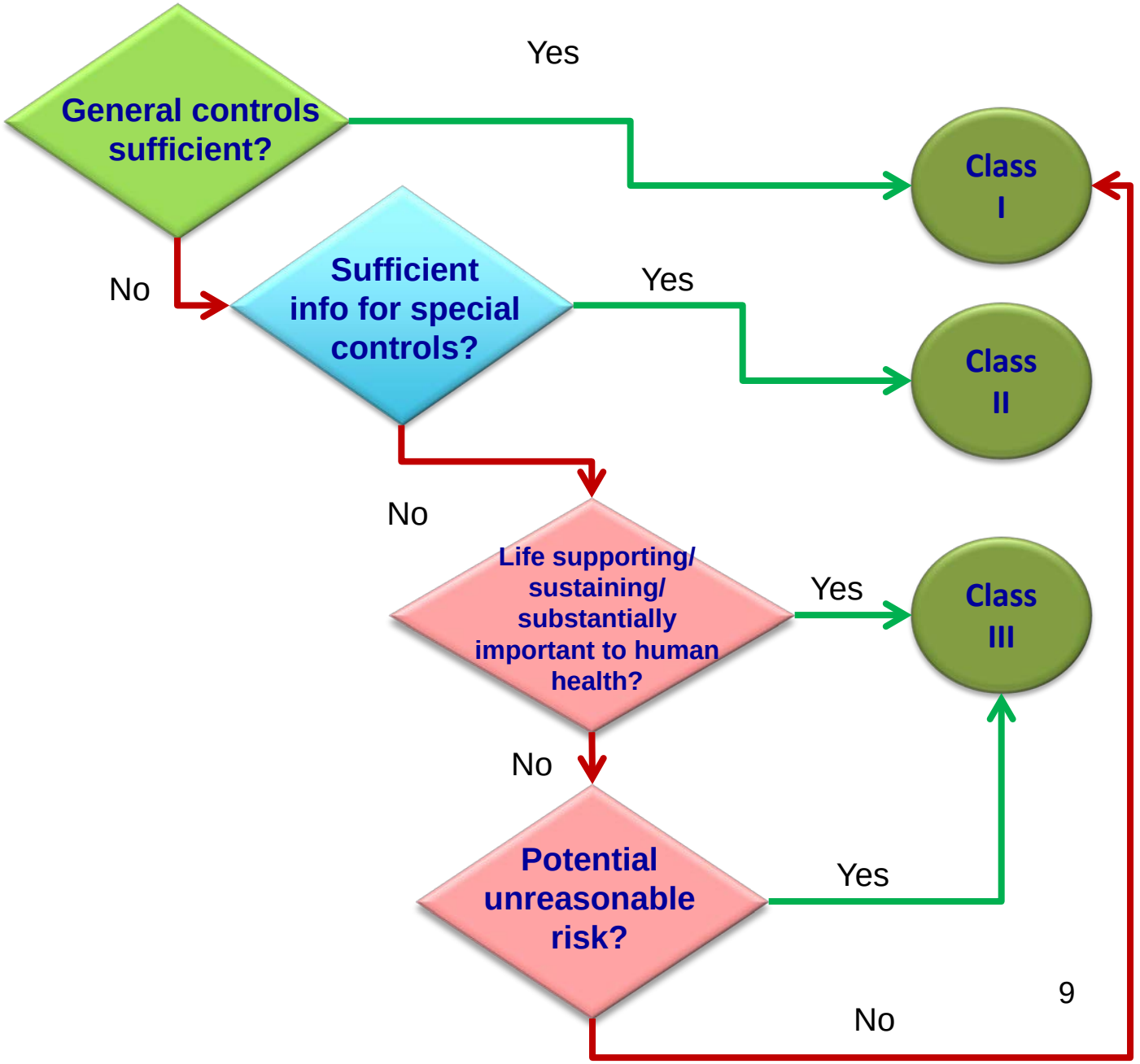
- Companies must provide evidence in their 510(k) submissions of how the special controls were addressed

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






General controls sufficient?
Yes
Class I
No
Sufficient info for special controls?
Yes
Class II
No
Life supporting/ sustaining/ substantially important to human health?
Yes
Class III
No
Potential unreasonable risk?
Yes
No

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Part 2: For four preamendments, 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 Is the Process?

Decision to start process is based on new information about the device, either on FDA's own initiative or upon the petition of an interested person. The Agency considers intended uses which have been reviewed by the Agency.

- Publish a proposed order announcing our proposed classification and seeking public comment
  - Completed on August 17, 2020 followed by 60 day comment period
- Convene a panel meeting to discuss proposed classification
  - Completed today.
- Consider public comments and all available information, including panel recommendations, prior to issuing a final order

What We Need from the Panel

- Review and discuss available scientific evidence regarding safety and effectiveness of non-invasive bone growth stimulators.
- Input and recommendations should include:
  - Identification of the risks to health presented by the device
  - 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 sufficient information exists to develop special controls
  - Identification of special controls
  - Whether general controls alone are sufficient

What Will Happen After This Panel Meeting?

- 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 I, devices may continue to be marketed
  - If Class II, existing devices may remain on the market provided they meet the designated special controls
  - If Class III, devices may continue to be marketed

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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 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 sufficient information exists to develop special controls
  - Identification of special controls
  - Whether general controls alone are sufficient

What Will Happen After This Panel Meeting?

- FDA will consider the available evidence, including the input of this panel and the public comments
- FDA will issue a proposed rule, proposing classification of the device and seeking public comment on the proposal
- 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, will issue a separate call for PMAs
    - Existing devices may remain on the market until submission of a PMA by specified time to continue marketing
    - If PMA is not approved, devices would be considered misbranded and must be removed from distribution


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