Device Classification

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Ophthalmic Devices Panel Meeting

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What is the Purpose of this Panel Meeting?

For ophthalmic dispensers, a preamendments, unclassified device type, you will be asked to provide input to FDA on the classification: 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

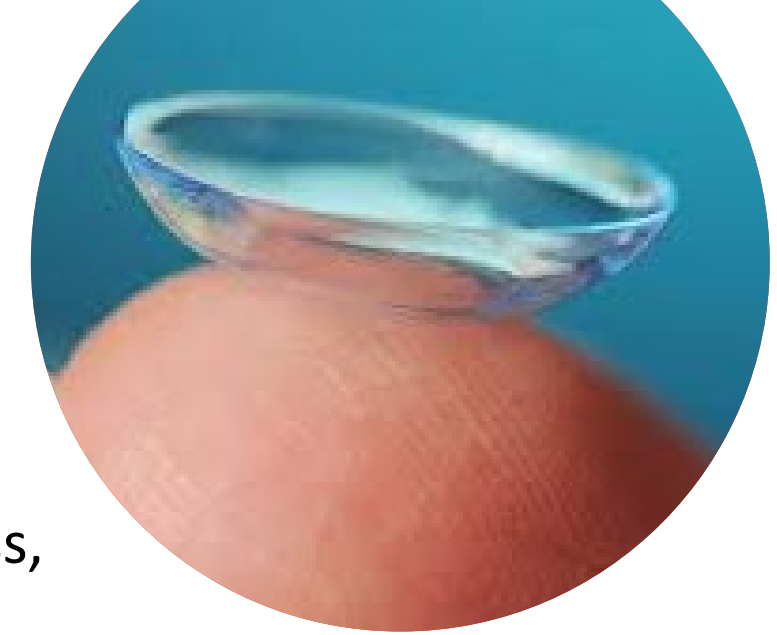
- Class I devices typically do not require FDA premarket review prior to being marketed

Class I Devices

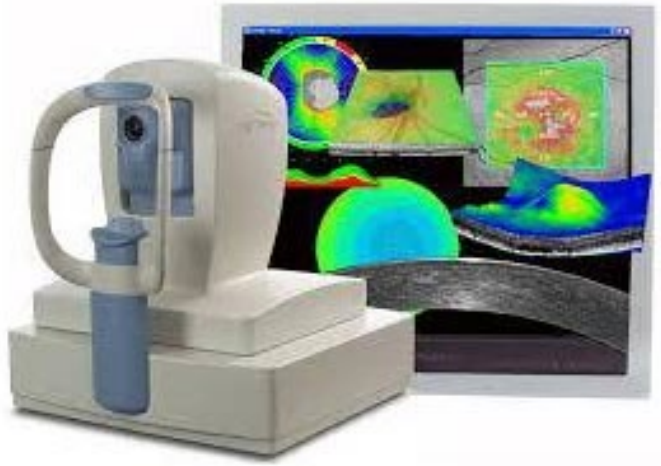
- Devices which cannot be classified into Class III:
  - Because they are not life-sustaining, life-supporting, of substantial importance in preventing impairment of human health, and
  - Because they do not present a potential unreasonable risk of illness or injury

- 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

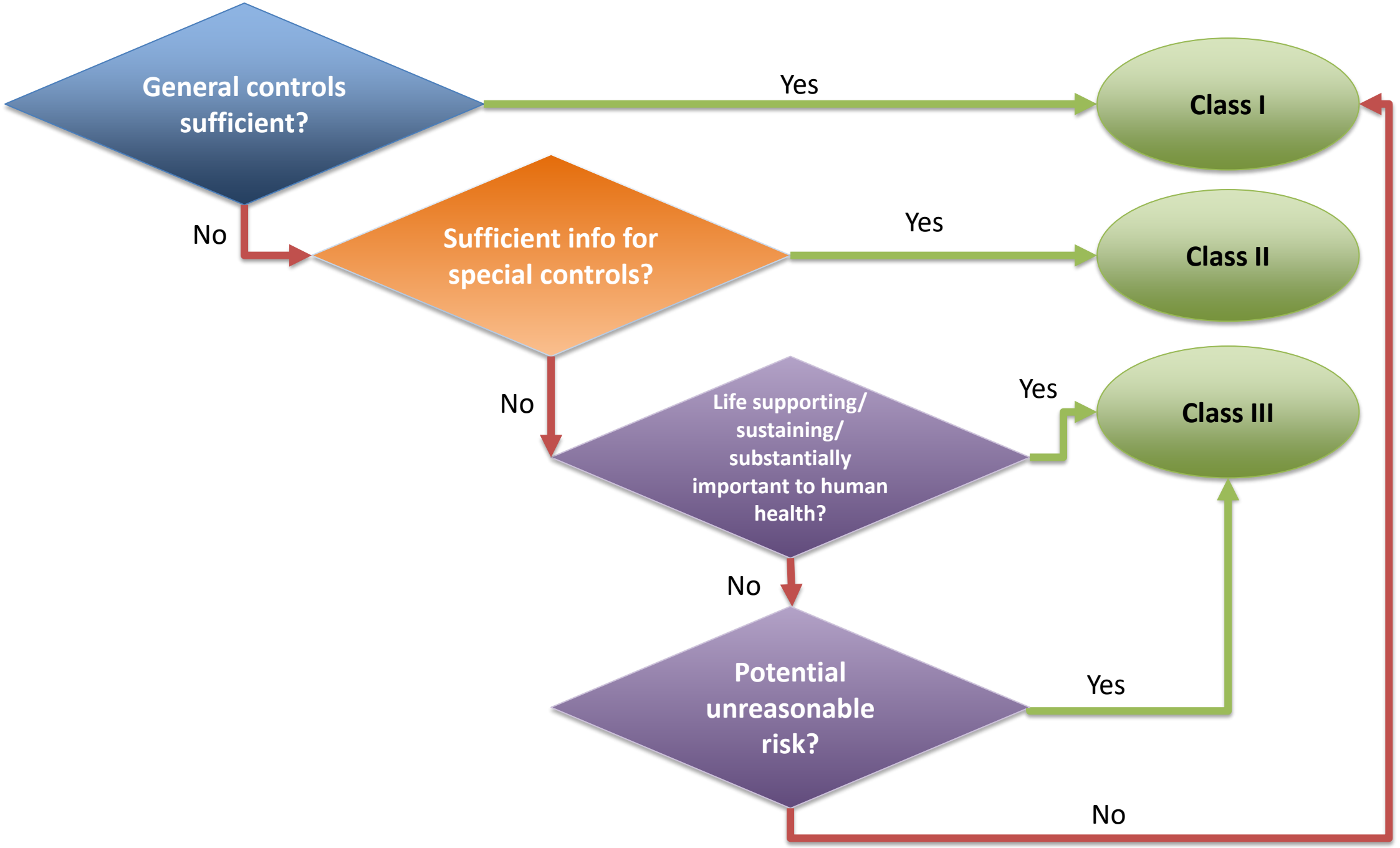
Class II Devices

- 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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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 type

- Class III, Class II, or Class I

Input should include:

- Identification of the risks to health presented by the 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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