

Device Classification

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**Radiologic Devices
Panel Meeting**

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What is the Purpose of this Panel Meeting?

For blood irradiators for prevention of metastasis, 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
- Examples of Class I devices include scintillation (gamma) cameras, radiographic head holders, radiographic anthropomorphic phantoms, and radiographic film marking systems.

Class I Devices

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

Class II Devices

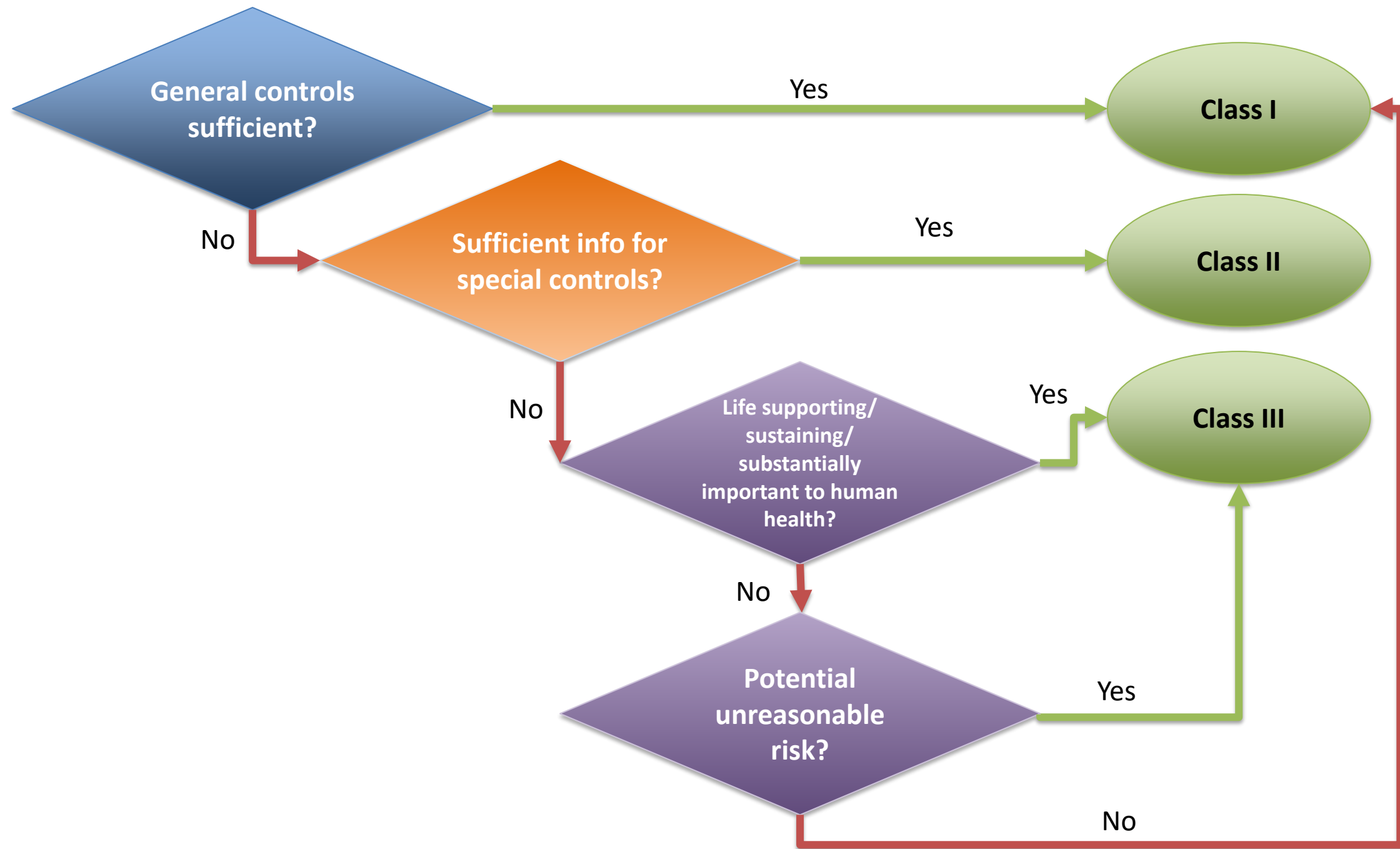
- Cannot be classified into Class I:
 - because general controls are insufficient to provide reasonable assurance of the safety and effectiveness, **and**
 - for which there is sufficient information to establish special controls to provide such assurance
- Special controls can include:
 - Performance testing
 - Sterilization validation
 - Device-specific labeling requirements
- These special controls, in combination with the general controls, provide reasonable assurance of safety and effectiveness
- Examples of Class II devices include full-field digital mammography systems, radiological computer aided triage and notification software, and rectal balloon for prostate immobilization devices.

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 special controls are sufficient to provide reasonable assurance of 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.
- Examples of Class III devices include transilluminator for breast evaluation devices, digital breast tomosynthesis systems, and radioactive microsphere devices.



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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

