Device Reclassification

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Reclassification of quantitative Cytomegalovirus (CMV) viral load devices from class III to class II.

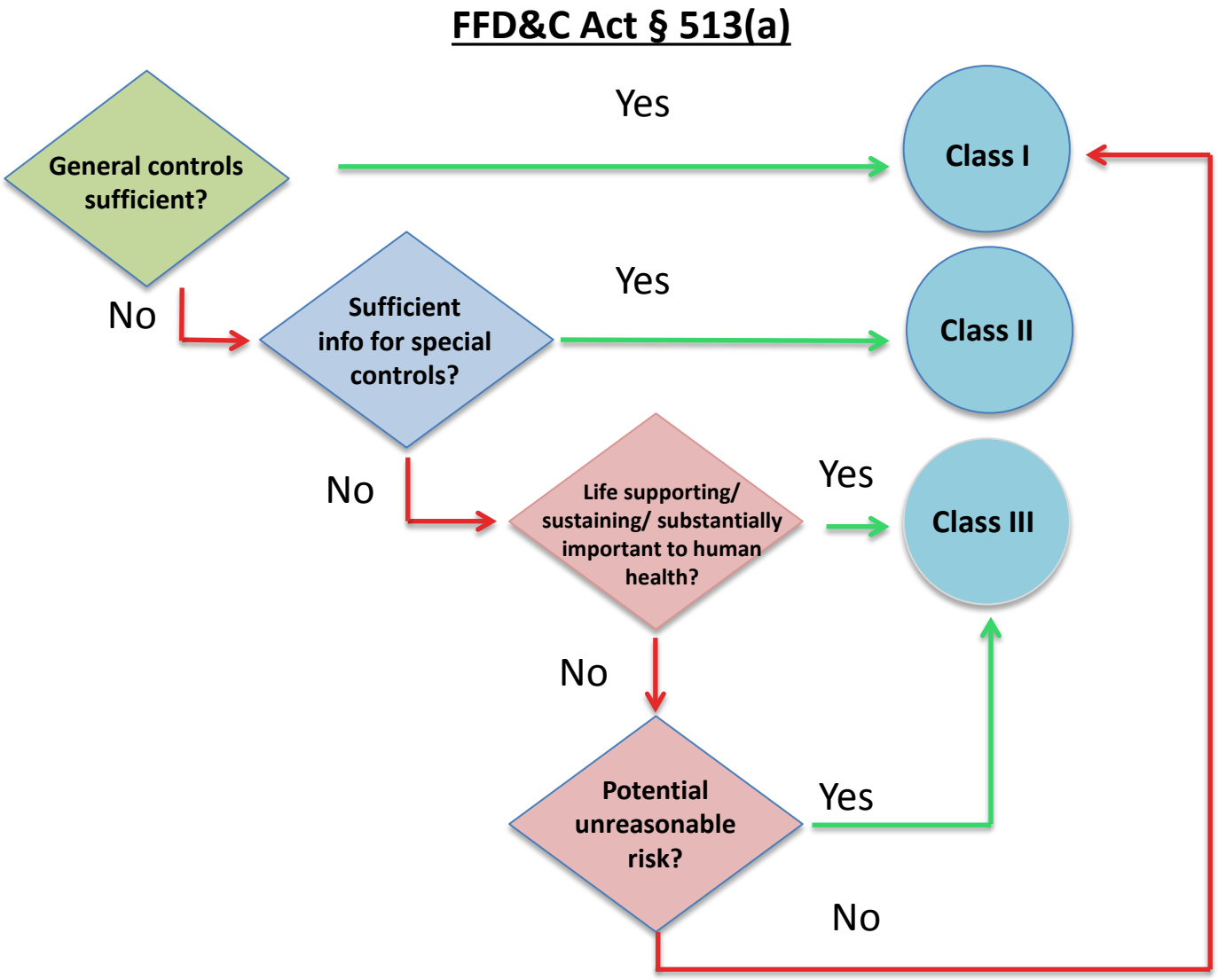
What Is the Purpose of This Panel Meeting?

- For the panel to address whether quantitative Cytomegalovirus (CMV) viral load devices classified as class III (PMA) should be reclassified to class II (510(k)). You will be asked to recommend whether they should remain in Class III (PMA), or be reclassified to Class II (510(k)).

What Is the Reclassification Process?

- FDA may reclassify a device classified into class III:
  - 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
- See FFD&C Act § 513(f)(3)

The Classification Flowchart



What Are General Controls?

- General Controls Include:
  - Prohibition against adulterated or misbranded devices,
  - Good Manufacturing Practices (GMPs)/Quality Systems,
  - Registration of manufacturing facilities,
  - Listing of device types,
  - Recordkeeping, etc.
- See FFD&C Act § 513(a)(1)(A)

What Are Special Controls?

- Special Controls include:
  - Performance standards
  - Postmarket surveillance
  - Patient registries
  - Development and dissemination of guidelines, etc.

- See FFD&C Act § 513(a)(1)(B)

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.

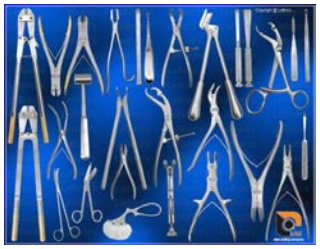
- See FFD&C Act § 513(a)(1)(A)

What Are 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 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 Surgical Instruments
- Manual Breast Pump
- Enema Kit



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 and clearance to FDA (i.e., a 510(k)) prior to being marketed.
- See FFD&C Act § 513(a)(1)(B)

What Are Some Examples of Class II Devices?

- Colonoscope
- Fetal Heart Monitor
- Gastrointestinal Feeding Tube
- Hemodialysis System

How Are Special Controls Used?

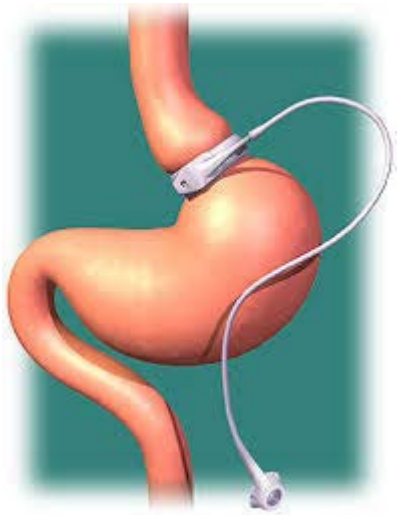
- As an example, *M. tuberculosis* complex IVDs were reclassified from Class III (PMA) to Class II (special controls).
- FDA issued a special controls guidance to mitigate risks to health:
  - Biocompatibility testing
  - Material characterization
  - Mechanical testing
  - Sterility
  - Labeling (warnings, 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.

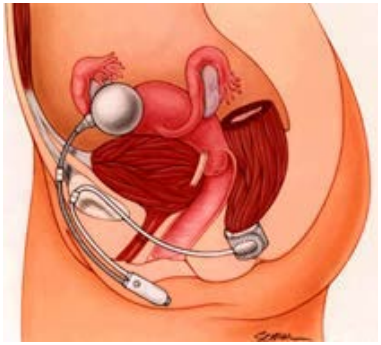
What Are Class III Devices?

- Cannot be classified into Class II because:
  - insufficient information exists to determine that general and specials 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
- See FFD&C Act § 513(a)(1)(C)

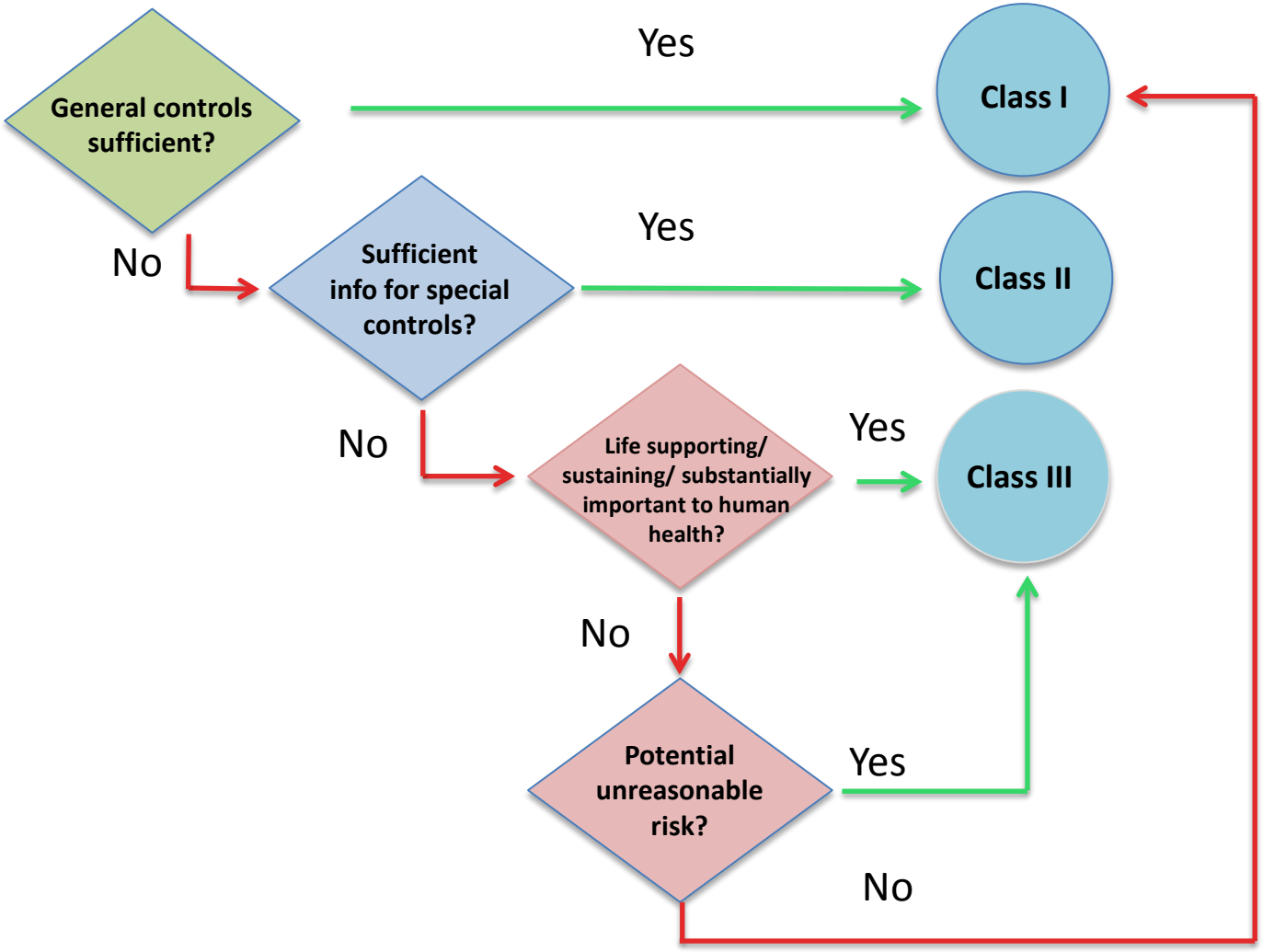
What Are Some Examples of Class III Devices?

- Extracorporeal Photophoresis System
- Obesity Treatment Device
- Implanted Urinary and Fecal Incontinence Device





The Classification Flowchart



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 will issue a proposed order, proposing classification of the device and seeking public comment on the proposal FDA may propose that the device type be reclassified as class II or remain in class III, or split the classification based on indications or technology.

- 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, existing class III devices may continue to be marketed, and will be reclassified to class II. Future devices will be able to come to market through the 510(k) clearance process.
  - If Class III, existing devices will remain on the market, future devices will continue to require a PMA.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