Device Classification

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Office of Health Technology 7: In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Microbiology Devices Panel of the
Medical Devices Advisory Committee
September 7, 2023

What Is The Purpose Of This Panel Meeting?

Discuss the available information for:

1. Hepatitis B Virus Antigen, Antibody, and Molecular Assays,
2. Parvovirus Antibody Assays, and
3. *Mycobacterium tuberculosis* Interferon Gamma Release Assays.

These tests are currently regulated as Class III devices, subject to premarket approval (PMA) and are under consideration for potential future reclassification into Class II (special controls) for which a premarket notification (510(k)) would be required.

FDA is seeking recommendations from the Panel members and the public on whether sufficient information exists such that the development of special controls (which along with general controls) could mitigate the risks from these devices such that the devices would provide a reasonable assurance of safety and effectiveness and therefore, can be eligible for a Class II designation.

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 of the device.

What Are Class I Devices?

- For which general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.
- Class I devices:
  - are generally subject to the lowest level of regulatory controls.
  - typically do not require FDA premarket review prior to being marketed
- Examples of Class I devices:
  - elastic bandages, hand-held manual surgical instruments, and differential culture mediums
- *See* section 513(a)(1)(A) of the FD&C Act.

What Are Class I Devices?

- Devices which cannot be classified into Class III:
  - Because they are not life supporting, life sustaining, 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 of the device.

What Are General Controls?

- General controls are basic statutory authorities found in the FD&C Act.
- General controls include, among other things:
  - Prohibition against adulterated or misbranded devices,
  - Good Manufacturing Practices (GMPs)/Quality Systems Requirements,
  - Registration and listing requirements,
    - Manufacturing facilities and device types
  - Adverse event reporting requirements,
  - Recordkeeping, etc.

- *See* sections 501, 502, 510, 516, 518, 519, and 520 of the FD&C Act.

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 are typically subject to premarket review and clearance to FDA (i.e., a 510(k)) prior to being marketed.
- Examples of Class II devices:
  - Intravascular administration sets (e.g., syringes), nucleic acid based IVDs for the detection of *Mycobacterium tuberculosis* complex, and endoscopes.
- *See* section 513(a)(1)(B) of the FD&C Act.

What Are Special Controls?

- Special controls may include:
  - Analytical testing (e.g, Limit of Detection, stability studies)
  - Clinical testing
  - Device-specific labeling requirements

- These special controls, in combination with the general controls, provide reasonable assurance of safety and effectiveness of the device.

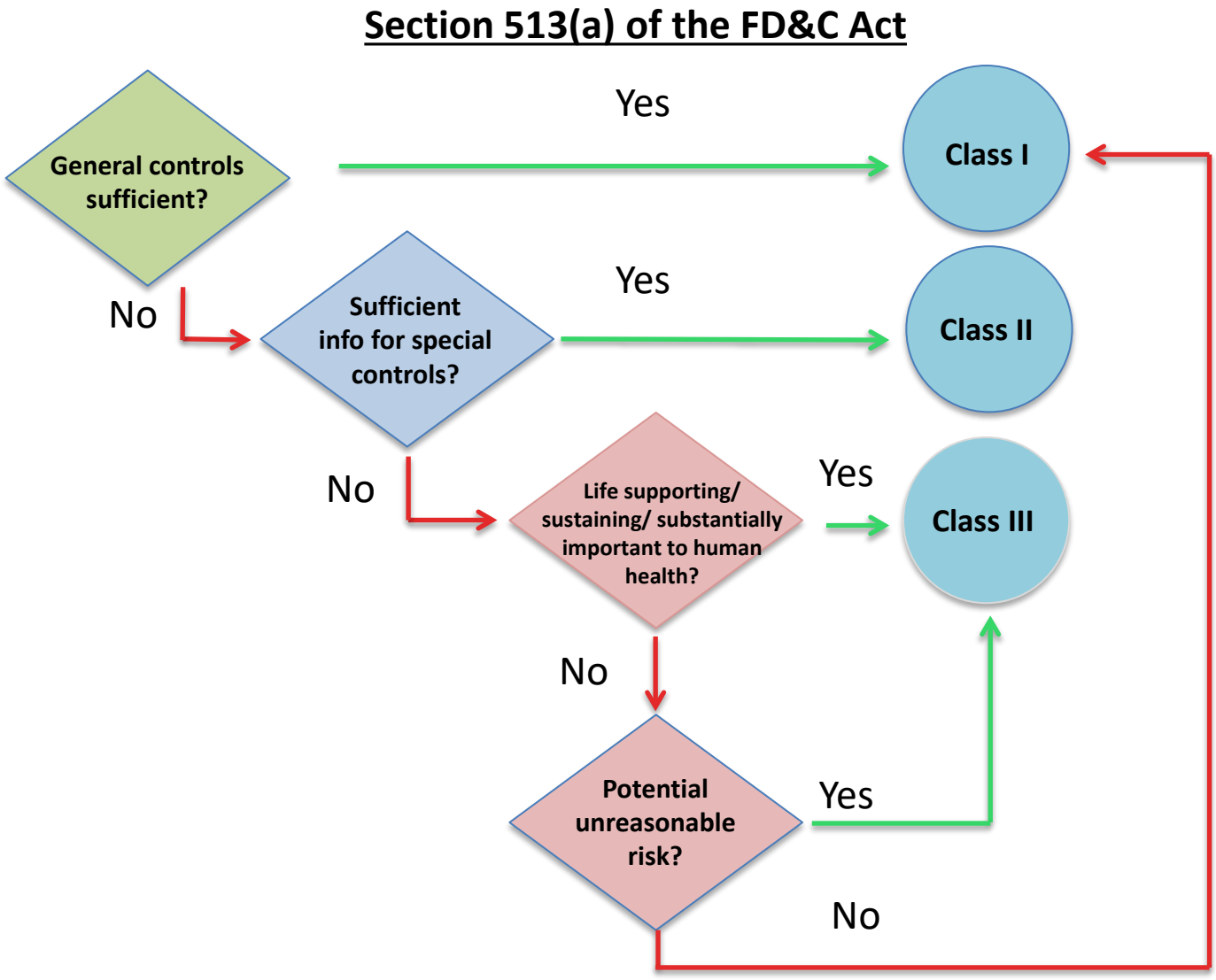
- Companies must provide evidence in their 510(k) submissions of how the special controls, as applicable, were addressed.

- *See* section 513(a)(1)(B) of the FD&C Act.

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 supporting or life sustaining, **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
- Examples of Class III devices:
  - Breast implants and IVDs for the Detection or Detection and Differentiation of Human Papillomaviruses
- *See* section 513(a)(1)(C) of the FD&C Act.

Device Classes



What We Need from the Panel

- Input and recommendations should include:
  - An identification of the risk(s) 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 such that the development of special controls (which along with general controls) could mitigate the identified risks
    - If so, identification and discussion of special controls
  - Input on current classification of the device(s) that are the subject of the Panel session and whether FDA should pursue reclassification of these devices

What Will Happen After This Panel Meeting?

- FDA will consider the available evidence, including the input from this panel meeting, for potential future reclassification of the device types discussed today.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