Classification of Intra-Abdominal Pressure Monitoring Devices
FDA Questions

Orthopaedic and Rehabilitation Devices Panel of Medical Devices Advisory Committee
September 8-9, 2020

1. FDA has identified the following risks to health for intra-abdominal pressure monitoring devices:

Identified Risk	**Description/Examples**
Adverse tissue reaction	This can result from the use of device materials that are not biocompatible.
Infection	This risk includes febrile reactions, inflammatory response syndromes, infection, sepsis, and microbial contamination.
Local tissue injury	This risk includes injury due to multiple possible factors such as incorrect placement, device failure/breakage, or excessive suction
Incorrect patient diagnosis	This risk could be due to errors in reading pressure measurements or incorrect device output or incorrect use of the device in a non-paralyzed patient making the results less clinically meaningful

Please comment on whether you agree with inclusion of all of the risks in the overall risk assessment of for intra-abdominal pressure monitoring devices under product code "PHU". In addition, please comment on whether you believe that any additional risks should be included in the overall risk assessment of these intra-abdominal pressure monitoring devices.

2. Section 513 of the Food, Drug, and Cosmetic Act states a device should be Class III if:

    - insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness or that application of special controls would provide such assurance, AND

    - if, in addition, the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.

A device should be Class II if:

- general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness, AND

- there is sufficient information to establish special controls to provide such assurance.

A device should be Class I if:

- general controls are sufficient to provide reasonable assurance of the safety and effectiveness, OR
- insufficient information exists to:
  - determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness, OR
  - establish special controls to provide such assurance, BUT
    I. is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and
    II. does not present a potential unreasonable risk of illness or injury.

FDA believes general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness and sufficient information exists to establish special controls to adequately mitigate the risks to health and provide reasonable assurance of device safety and effectiveness for this device type. As such, FDA believes that Class II is the appropriate classification for intra-abdominal pressure monitoring devices. Following is a risk/mitigation table which outlines the identified risks to health for this device type and the recommended controls to mitigate the identified risks.

Risk/mitigation recommendations for intra-abdominal pressure monitoring devices under product code "PHU"

Identified Risk	**Recommended Mitigation Measure**
Adverse tissue reaction	Biocompatibility evaluation
Infection	Sterilization validation Shelf life testing Labeling
Local tissue injury	Labeling Performance Testing – Bench
Incorrect patient diagnosis	Performance Testing – Bench Labeling

Please discuss whether the identified special controls for intra-abdominal pressure monitoring devices appropriately mitigate the identified risks to health and whether additional or different special controls are recommended:

1. Non-clinical performance testing data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
    i) Mechanical bench testing of material strength must demonstrate the device will withstand forces encountered during use and maintain device integrity upon repeated actuation/measurements.
    ii) Performance testing should validate clinically relevant pressure range and ensure the pressure ranges used do not cause inadvertent damage to underlying tissue.
    iii) Performance testing must demonstrate proper function and accurate pressure measurement.
2. The device must be demonstrated to be biocompatible.
3. Validation testing must demonstrate the sterility of the device.
4. Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.
5. The labeling must include all adequate warnings/precautions and instructions regarding the proper placement and use of the device.

3. Please discuss whether you agree with FDA's proposed classification of Class II with special controls for intra-abdominal pressure monitoring devices. If you do not agree with FDA's proposed classification, please provide your rationale for recommending a different classification.