Classification of Intra-Abdominal Pressure Monitoring Devices Under Product Code PHU

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Intra-Abdominal Pressure Monitoring Devices (PHU)

- Intended for monitoring of pressure in the abdominal compartment to aid in the diagnosis of abdominal compartment syndrome.
- Regulated under product code “PHU” as “Intra-abdominal Pressure Monitoring Device”.
- Since it is unclassified, there is no regulation associated with the product code.
- There have been 2 clearances for intra-abdominal pressure monitoring devices via the 510(k) process (1970-2020).

Indications for Use

- Intended for monitoring of intra-abdominal pressure via a Foley urinary catheter. The measured pressures can be used as an aid in the diagnosis of intra-abdominal hypertension (IAH) and the associated clinical syndrome of abdominal compartment syndrome (ACS).
- Intended for use in the monitoring of intra-abdominal pressure. The measured pressures can be used as an aid in the diagnosis of intra-abdominal hypertension (IAH) and the associated clinical syndrome of abdominal compartment syndrome (ACS).

Determination of Risks: Medical Device Reports & Literature Review

- Manufacturer and User facility Device Experience (MAUDE) database (up to 2019)
- Information available to FDA regarding cleared devices
- Review of literature

Literature Review

- A systematic literature review was conducted in an effort to gather any published information regarding the safety and effectiveness of intracompartmental pressure monitors under product code “PHU”.
- Literature searches were conducted to identify any relevant articles published up to and including October 31, 2019.
- The searches were limited to publications in English and excluded conference proceeding and abstracts.
- Based upon a review of the published literature, we could not identify any reports describing complications with use of an intra-abdominal pressure monitor under product code “PHU”

Medical Device Reports - Summary

Event Type	Count
Malfunction	51
Death	5
Total	**56**

Risks and Mitigations

- Adverse tissue reaction
- Infection
- Local tissue injury
- Incorrect patient diagnosis

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Risks and Mitigations (cont'd)

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

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Proposed Classification Regulation

878.XXXX Intra-Abdominal Pressure Monitoring Device

(a) *Identification.* An intra-abdominal pressure monitoring device is a prescription device that monitors pressure in the abdominal compartment to aid in the diagnosis of abdominal compartment syndrome.

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Proposed Classification Regulation

878.XXXX Intra-abdominal Pressure Monitoring Devices

(b) *Classification.* Class II (special controls)

We propose the following special controls for these devices:

- 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:
  - Mechanical bench testing of material strength must demonstrate the device will withstand forces encountered during use and maintain device integrity upon repeated actuation/measurements.
  - Performance testing should validate clinically relevant pressure range and ensure the pressure ranges used do not cause inadvertent damage to underlying tissue.
  - Performance testing must demonstrate proper function and accurate pressure measurement.
- The device must be demonstrated to be biocompatible.
- Validation testing must demonstrate the sterility of the device.
- Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.
- The labeling must include all adequate warnings/precautions and instructions regarding the proper placement and use of the device.

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Questions to Panel

PHU

End of Panel Questions for Product Codes “PHU”

Question 1: Introduction

FDA has identified the following risks to health for intra-abdominal pressure monitoring devices under product code “PHU” based upon FDA’s review of literature, information available to FDA regarding the cleared devices and the Manufacturer and User facility Device Experience (MAUDE) database:

- Adverse tissue reaction
- Infection
- Local tissue injury
- Incorrect patient diagnosis

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Question 1 to Panel

Please comment on whether you whether you agree with inclusion of all of the risks in the overall risk assessment of the 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 the intra-abdominal pressure monitoring devices.

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Question 2: Introduction Classes III and II

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
- 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.

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Question 2 Introduction Class I

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.

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Question 2 Introduction

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 the intra-abdominal pressure monitoring devices under product code “PHU”. 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.

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Question 2 Risks to Health

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

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Question 2 to Panel

Please discuss whether the following special controls appropriately mitigate the identified risks to health and whether additional or different special controls are recommended.

- 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:
  - Mechanical bench testing of material strength must demonstrate the device will withstand forces encountered during use and maintain device integrity upon repeated actuation/measurements.
  - Performance testing should validate clinically relevant pressure range and ensure the pressure ranges used do not cause inadvertent damage to underlying tissue.
  - Performance testing must demonstrate proper function and accurate pressure measurement.
- The device must be demonstrated to be biocompatible.
- Validation testing must demonstrate the sterility of the device.
- Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.
- The labeling must include all adequate warnings/precautions and instructions regarding the proper placement and use of the device.

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Question 3 to Panel

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.

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