FDA Executive Summary

Prepared for the September 8-9, 2020 Meeting of the Orthopaedic and Rehabilitation Devices Advisory Panel

Classification of Intra-Abdominal Pressure Monitoring Devices

Product Code: PHU

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1. Introduction

Per Section 513(b) of the Food, Drug, and Cosmetic Act (the Act), the Food and Drug Administration (FDA) is convening the Orthopaedic and Rehabilitation Devices Advisory Panel (the Panel) for the purpose of obtaining recommendations regarding the classification of intra-abdominal pressure monitoring devices, a pre-amendments device type that remains unclassified. Specifically, the FDA will ask the Panel to provide recommendations regarding the regulatory classification of intra-abdominal pressure monitoring devices under product code "PHU." The device names and associated product codes are developed by the Center for Devices and Radiological Health (CDRH) in order to identify the generic category of a device for FDA. While most of these product codes are associated with a device classification regulation, some product codes, including "PHU" remain unclassified.

FDA is holding this panel meeting to obtain input on the risks to health and benefits of intra-abdominal pressure monitoring devices under product code "PHU." The Panel will discuss whether intra-abdominal pressure monitoring devices under product code "PHU" should be classified into Class II (subject to General and Special Controls). If the Panel believes that classification into Class II is appropriate for intra-abdominal pressure monitoring devices under product code "PHU," the Panel will also be asked to discuss appropriate controls that would be necessary to mitigate the risks to health.

1.1 Current Regulatory Pathways

Intra-abdominal pressure monitoring devices are a pre-amendments, unclassified device type. This means that this device type was marketed prior to the Medical Device Amendments of 1976 but was not classified by the original classification panels. Currently these devices are being regulated through the 510(k) pathway and are cleared for marketing if their intended use and technological characteristics are "substantially equivalent" to a legally marketed predicate device. Since these devices are unclassified, there is no regulation associated with the product code.

1.2 Device Description

The device is intended for monitoring of pressure in the abdominal compartment to aid in the diagnosis of abdominal compartment syndrome. Using a Foley catheter, pressure in the urinary bladder is measured as an indirect measure of intra-abdominal pressure.

2. Regulatory History

The Bard Intra-Abdominal Pressure Monitoring Device Model IAP-001 was the first device cleared under product code PHU on August 1, 2007. The predicate device was the Twin Star Compartment Syndrome Pressure Monitoring and Fluid Collection Catheter System (K041771), under product code LXC (intracompartmental pressure monitor), which is also an unclassified device type. The product code PHU was created to distinguish the devices based upon anatomical location (i.e., those for use in intra-abdominal pressure monitoring vs. those for use in extremity pressure monitoring).

In addition, the Accuryn Monitoring System was cleared with PHU as a secondary product code. This device uses a multi-lumen catheter for the drainage and/or collection of urine, monitoring urine output, and monitoring core body temperature, as well as measuring intra-abdominal pressure.

Table 1: 510(k) Clearances for Intra-Abdominal Pressure Monitoring Devices under Product Code "PHU"

510(k) Number	Trade Name	Sponsor
K070201	Bard Intra-Abdominal Pressure Monitoring Device, Model IAP-001	C.R. Bard, Inc.
K153655*	Accuryn Monitoring System	Potrero Medical, Inc.

*PHU as secondary product code

3. Indications for Use

The Indications for Use (IFU) statement identifies the condition and patient population for which a device should be appropriately used.

Table 2: Indications for Use of 510(k)-Cleared Devices under Product Code "PHU"

510(k) Number	Indications for Use
K070201	The Bard Intra-abdominal Pressure (IAP) Monitoring Device is 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).
K153655 (relevant indications in *italics*)	The Accuryn Monitoring System is intended for use in the drainage and/or collection of urine, and in the monitoring of urine output and core body temperature, in degrees Fahrenheit and degrees Celsius. *The Accuryn Monitoring System is also 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).* The Accuryn Sensing Urinary Catheter is a single use device intended for short-term use (less than 30 days)

4. Clinical Background

4.1 Disease Characteristics

Abdominal compartment syndrome (ACS) describes increasing organ dysfunction or failure as a result of sustained intra-abdominal hypertension (IAH) which causes decreased perfusion to end organs (such as the kidneys) and can negatively impact pulmonary mechanics due to increased pressure on the diaphragm. IAH is present when there is a consistent increased intra-abdominal pressure, higher than 12 mmHg, determined by a minimum of three pressure measurements conducted 4 to 6 hours apart, measured at the end of expiration in a supine and fully relaxed or pharmacologically-paralyzed patient. Increased abdominal pressure can occur due to various pathological states like trauma, intestinal perforation or edema, bleeding, infection or over resuscitation of intravenous fluids. Once the diagnosis of ACS is made, the most common treatment is a decompressive laparotomy where the abdomen is opened and fluids suctioned out to prevent progressive end organ dysfunction and ultimately patient death. Although ACS is a clinical diagnosis, the use of intra-abdominal pressure monitors remains a mainstay of the diagnostic work up to aid clinicians in decision making.

4.2 Patient Outcomes

Intra-abdominal pressure (IAP) is measured with these devices and graded on a scale. Grade I is IAP 10 – 15 mmHg, Grade II is 16 – 25 mmHg, Grade III is 26 – 35 mmHg, and Grade IV is > 36 mmHg.

Currently, the gold standard diagnosis of IAH is via intra-abdominal pressure monitoring devices that use bladder pressure as a surrogate for measuring abdominal pressure. These devices are useful because early proactive diagnosis of increasing abdominal pressure and IAH is often an indication to proceed to the operating room for decompressive laparotomy prior to patients developing ACS with end organ dysfunction or failure.

Most patients who develop IAP Grade II (Pressure of 16 – 25 mmHg) and above often have some component of organ dysfunction and are therefore recommended for decompressive laparotomy to relieve the pressure within the abdominal compartment.

4.3 Currently Available Treatment

The standard of care treatment for increased abdominal pressure leading to organ dysfunction is decompressive laparotomy where the abdomen is opened and pressure is therefore normalized to atmospheric pressure. In patients with a large volume of ascites and IAP or IAH that have not yet developed ACS, some studies have looked at the role of paracentesis and drain placement that functionally acts to decrease the abdominal pressure via drainage of fluid from the abdomen. This is an option for some patients where large volumes of intra-abdominal fluid are present and where laparotomy would carry a higher risk of morbidity or mortality.

4.4 Risks

FDA has identified the following risks to health associated with intra-abdominal pressure monitoring devices:

Table 3: Risks to Health and Descriptions/Examples 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

The Panel will be asked whether this list is a complete and accurate list of the risks to health presented by intra-abdominal pressure monitoring devices under product code "PHU" and whether any other risks should be included in the overall risk assessment of the device type.

5. Literature Review

5.1 Methods

A systematic literature review was conducted in an effort to gather any published information regarding the safety and effectiveness of intra-abdominal pressure monitoring devices under product code "PHU."

Literature searches to identify any relevant articles published up to and including October 31, 2019 were conducted. The searches were limited to publications on human studies in English and excluded conference proceedings and abstracts.

The search used the following terms:

- "intra-abdominal pressure monitor"
- "intra-abdominal pressure device"
- "IAP monitor"

5.2 Results

A search of the exact phrase “intra-abdominal pressure monitor” yielded two publications citing simulation studies and no relevant results.

Using broad search terms “intra-abdominal pressure device” yielded 333 references. The search terms “IAP monitor” yielded 133 references. Nearly all relevant references correlate intra-abdominal pressure with intra-abdominal hypertension and abdominal compartment syndrome. The specific use of an intra-abdominal pressure device is not evaluated in the references yielded from these search terms.

Based on 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.”

6. Risks to Health Identified through Medical Device Reports (MDRs)

6.1 Overview of the MDR System

The MDR system provides FDA with information on medical device performance from patients, health care professionals, consumers and mandatory reporters (manufacturers, importers and device user facilities). The FDA receives MDRs of suspected device-associated deaths, serious injuries, and certain malfunctions. The FDA uses MDRs to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. MDRs can be used effectively to:

- Establish a qualitative snapshot of adverse events for a specific device or device type
- Detect actual or potential device problems used in a “real world” setting/environment

Although MDRs are a valuable source of information, this passive surveillance system has limitations, including the submission of incomplete, inaccurate, untimely, unverified, duplicated or biased data. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about the frequency of device use. Finally, the existence of an adverse event report does not definitely establish a causal link between the device and the reported event. Because of these limitations, MDRs comprise only one of the FDA’s tools for assessing device performance. As such, MDR numbers and data should be taken in the context of the other available scientific information.

6.2 MDR Data: Intra-Abdominal Pressure Monitoring Devices

Individual MDRs for intra-abdominal pressure monitoring devices are reported through FDA's Manufacturer and User Facility Device Experience (MAUDE) Database, which houses mandatory reports from medical device manufacturers, importers and user facilities, as well as voluntary reports from entities such as health care professionals, patients and consumers.

The FDA conducted queries of the database for intra-abdominal pressure monitoring devices and this search resulted in the identification of 56 MDRs.

The reported adverse events fall primarily into the following categories (please note that multiple adverse events may be reported in a single MDR):

Table 4: MDR Events for Intra-Abdominal Pressure Monitoring Devices

Event Type	Count
Malfunction	51
Death	5
Total	56

Five MDR events listed as Death were linked to the same event in which the patient had ACS and likely died as a result. These five reports had no additional evidence as the complainant/reporter was unable or unwilling to provide any patient, product, or procedural details to the manufacturer. As such, insufficient data exist to suggest that the cause of death was device-related.

7. Recall History

7.1 Overview of Recall Database

The Medical Device Recall database contains Medical Device Recalls classified since November 2002. Since January 2017, it may also include correction or removal actions initiated by a firm prior to review by the FDA. The status is updated if the FDA identifies a violation and classifies the action as a recall and again when the recall is terminated. FDA recall classification may occur after the firm recalling the medical device product conducts and communicates with its customers about the recall. Therefore, the recall information posting date ("create date") identified on the database indicates the date FDA classified the recall, it does not necessarily mean that the recall is new.

7.2 Recall Results: Intra-Abdominal Pressure Monitoring Devices "PHU"

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm

A search of for products under product code "PHU" resulted in no relevant recalls.

8. Summary

In light of the information available, the Panel will be asked to comment on whether intra-abdominal pressure monitoring devices under product code "PHU":

meet the statutory definition of a Class III device:

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

or would be more appropriately regulated as Class II, in which:

- general and special controls, which may include performance standards, postmarket surveillance, patient registries and/or development of guidelines, are sufficient to provide reasonable assurance of safety and effectiveness;

or as Class I, in which:

- the device is subject only to general controls, which include registration and listing, good manufacturing practices (GMPs), prohibition against adulteration and misbranding, and labeling devices according to FDA regulations.

For the purposes of classification, FDA considers the following items, among other relevant factors, as outlined in 21 CFR 860.7(b):

1. The persons for whose use the device is represented or intended;

2. The conditions of use for the device, including conditions of use prescribed, recommended, or suggested in the labeling or advertising of the device, and other intended conditions of use;

3. The probable benefit to health from the use of the device weighed against any probable injury or illness from such use; and

4. The reliability of the device.

8.1 Special Controls

FDA believes that special controls, in addition to general controls, can be established to mitigate the risks to health identified, and provide a reasonable assurance of the safety and effectiveness of 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:

Table 5: Summary of Risks to Health and Proposed Special Controls for Intra-Abdominal Pressure Monitoring Devices

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

If the Panel believes that Class II is appropriate for intra-abdominal pressure monitoring devices under product code "PHU," the Panel will be asked whether the identified special controls appropriately mitigate the identified risks to health and whether additional or different special controls are recommended.

Based on the identified risks and recommended mitigation measures, FDA believes that the following special controls would provide reasonable assurance of safety and effectiveness for intra-abdominal pressure monitoring devices under product code "PHU":

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 must validate a 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.

If the Panel believes that Class II is appropriate for intra-abdominal pressure monitoring devices under product code "PHU," the Panel will be asked whether the identified special controls appropriately mitigate the identified risks to health and whether additional or different special controls are recommended.

8.2 Overview of Proposed Classification/FDA Recommendation

Based on the safety and effectiveness information gathered by the FDA, the identified risks to health and recommended mitigation measures, we recommend that intra-abdominal pressure

monitoring devices indicated for use in the monitoring of intra-abdominal pressure be regulated as Class II devices.

878.XXXX Intra-abdominal pressure monitoring device.

(a) *Identification. An intra-abdominal pressure monitoring device is a device for use in monitoring intra-abdominal pressure.*

(b) *Classification.*
Class II (special controls). The special controls for this device are:

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.

Based on the available scientific evidence, the FDA will ask the Panel for their recommendation on the appropriate classification of the intra-abdominal pressure monitoring devices under product code "PHU."