FDA Executive Summary

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

Classification of Intracompartmental Pressure Monitors

Product Code: LXC (Monitor, Pressure, Intracompartmental)

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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 Panel (the Panel) for the purpose of obtaining recommendations regarding the classification of intracompartmental pressure monitors, a pre-amendments device type that remains unclassified. Specifically, the FDA will ask the Panel to provide recommendations regarding the regulatory classification of intracompartmental pressure monitors under product code "LXC." 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 "LXC," remain unclassified.

FDA is holding this panel meeting to obtain input on the risks to health and benefits of intracompartmental pressure monitors under product code "LXC." The Panel will discuss whether the intracompartmental pressure monitors under product code "LXC" should be classified into Class III (subject to General Controls and Premarket Approval), Class II (subject to General and Special Controls), or Class I (subject only to General Controls). If the Panel believes that classification into Class II is appropriate for the intracompartmental pressure monitors under product code "LXC," 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

Intracompartmental pressure monitors are a pre-amendment, 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 intracompartmental pressures to aid in the diagnosis of compartment syndrome, defined as a condition in which the circulation and function of tissues within a closed space are compromised by increased pressure within the space.

The cleared devices use one of two methods to measure pressure. The first method consists of a fluid-filled slit catheter inserted in the compartment and uses an arterial line transducer to measure pressure. The catheter may be in-dwelling, and pressure monitoring may be continuous. The second method employs a syringe-based manometer to measure the resistance present when a small volume of saline solution is injected into the compartment. This design is used for

intermittent measurements. Some catheter-based devices also include a vacuum pump to remove fluid for analysis.

2. Regulatory History

The Compartment Syndrome Pressure Monitor System manufactured by Stryker Corporation was the first LXC device cleared on April 4, 1985. The sponsor noted that prior to 1976, compartmental pressure was measured by piecing together components rather than employing an integrated system. The sponsor cited substantial equivalence of individual components to preamendment devices or legally marketed predicates: the needle, cannulated needle (trocar) and placement cannula (sheath) distributed by Argyle prior to 1976; the slit (indwelling) catheter marketed by Howmedica and cleared in 1980 (K803093); the miniature pressure transducer marketed by Bell and Howell prior to 1976; and Hewlett Packard Model 78205D Pressure Module and Gould Physiological Pressure Monitor Module SP1405B patient fluid monitors. To date, the FDA has cleared a total of eight devices under this product code: seven intracompartmental pressure monitors and one needle to be used with a cleared monitor.

Please refer to Table 1 for a listing of the manufacturers, device names, and associated 510(k) submission numbers for cleared intracompartmental pressure monitors under product code "LXC":

Table 1: 510(k) Clearances for Intracompartmental Pressure Monitors under Product Code "LXC"

510(K) NUMBER	TRADE NAME	SPONSOR
K131966	TWIN STAR EXTREMITY COMPARTMENT SYNDROME MONITOR AND FLUID COLLECTION CATHETER SYSTEM	TWIN STAR MEDICAL, INC.
K090961	TWIN STAR COMPARTMENT PRESSURE MONITOR AND FLUID COLLECTION CATHETER SYSTEM (CMS-II)	TWIN STAR MEDICAL, INC.
K060963	TWIN STAR COMPARTMENT PRESSURE MONITORING AND FLUID COLLECTION MONITOR (CMS MONITOR)	TWIN STAR MEDICAL, INC.
K041771	TWIN STAR COMPARTMENT PRESSURE MONITORING AND FLUID COLLECTION CATHETER SYSTEM	TWIN STAR MEDICAL, INC.
K031555	SYNTHES (USA) COMPARTMENTAL PRESSURE MONITORING SYSTEM	SYNTHES (USA)
K881858	ACE ICPM SIDE PORTED NEEDLE	BUCKMAN CO., INC.
K873684	ACE INTRACOMPARTMENTAL PRESSURE MONITOR	ACE MEDICAL CO.
K844214	COMPARTMENT SYNDROME PRESSURE MONITOR SYSTEM	STRYKER CORP.

3. Indications for Use

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

The devices are intended for the immediate, intermittent, or continuous measurement of intracompartmental pressures in patients with known or suspected cases of compartment syndrome or conditions that may lead to increasing levels of intracompartmental pressure. The devices may also allow for the withdrawal of fluid for subsequent analysis. The measured intracompartmental pressures can be used as an aid in the diagnosis of compartment syndrome.

4. Clinical Background

4.1 Disease Characteristics

Compartment syndrome occurs when excessive pressure develops within an enclosed muscle or organ space in the body and adversely impacts the circulation and function of tissues within that space. In the extremities, groups of muscles are organized into regions, or compartments, which are formed by strong webs of connective tissue called fascia. When the tissue volume in a muscle compartment increases due to edema or collection of fluid, the tough walls of fascia cannot easily expand, leading to reduction in tissue perfusion. If this rise in compartment pressure remains untreated, inadequate blood flow to tissues inside the compartment may result in muscle necrosis, nerve damage, loss of extremity functions, amputation, or even death. The life-threatening component is related to rhabodomyolysis leading to myoglobinuria and acute renal failure.

Compartment syndrome affecting the extremities is classified as acute or chronic. Acute compartment syndrome is the most common type of compartment syndrome and is most often due to trauma. The incidence of acute compartment syndrome has been estimated to be 7.3 cases per 100,000 in males and 0.7 cases per 100,000 in females (McQueen, et al., 2000). Acute compartment syndrome occurs more commonly in males younger than 35, which may be due to a larger relative intracompartmental muscle mass and increased likelihood of being involved in high energy trauma. Approximately 75% of cases of acute compartment syndrome are caused by a fracture of the leg or arm, with tibial shaft fractures representing the most common etiology. Other causes of acute compartment syndrome include traumatic injuries without fracture such as vascular injury, crush injury, penetrating trauma, extrinsic compression by casts or splints, burns, injection injuries, animal bites or stings, and ischemia due to extended periods of limb compression in individuals with alterations in mental status due to drug overdose. Compartment syndrome may also develop due to nontraumatic etiologies such as bleeding disorders, extravasation of intravenous fluids, and infections. The signs and symptoms of acute compartment syndrome include pain out of proportion to the magnitude of the injury, pain with passive muscle stretching, paresthesia, palpable tenseness of the compartment, muscle weakness, paralysis, and, rarely, reduction in distal pulses.

Chronic compartment syndrome, also called exertional compartment syndrome, is associated with regular vigorous exercise and is relieved with rest. The lower leg, buttock, or thigh is usually involved, and it tends to resolve once the extremity has been rested. This condition rarely rises to the level of an emergency.

Another form of compartment syndrome, abdominal compartment syndrome, is not addressed in this classification but is the focus of a different classification before this Panel, for product code PHU, the intra-abdominal pressure monitoring device.

4.2 Patient Outcomes

Prompt surgical treatment is indicated for acute compartment syndrome to reduce intracompartmental pressure and avoid negative sequellae. Although reduction in intracompartmental pressure can restore tissue perfusion, complications are common for those undergoing treatment with fasciotomy. Nearly one-third of patients receiving fasciotomies will end up with a postoperative complication including soft tissue necrosis, wound dehiscence, delayed healing, skin graft infection or necrosis, or the need for additional tissue debridement procedures. Despite treatment, many patients experience adverse impact on quality-of-life and chronic problems with their injured extremity.

4.3 Currently Available Treatment

Acute compartment syndrome is a surgical emergency, so prompt diagnosis and treatment are critical. Early diagnosis is predicated on a high index of clinical suspicion and supported by history and clinical examination findings. Pressure-based methods of diagnosis are recommended due to the limited sensitivity and specificity of clinical examination in fully conscious patients, as well as the inability to assess those patients with a depressed level of consciousness (i.e., obtunded). Diagnostic issues to take into consideration include variability in the thresholds for fasciotomy, timing, and method of pressure monitoring (single reading versus continuous versus intermittent measurement). Non-surgical treatment for acute compartment syndrome is generally inadequate. Immediate treatment includes removing all external wraps, splints, and casts, lowering the affected limb to improve blood flow, providing nasal oxygen, administering IV fluids to prevent hypotension, and pain medication. Definitive treatment consists of surgery to perform a fasciotomy of the involved compartments.

Chronic compartment syndrome can first be treated by avoiding the activity that caused it and with stretching and physical therapy exercises. Surgery is not as urgent in chronic or exertional compartment syndrome, but in some instances, it may be required to relieve pressure.

4.4 Risks

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

Table 2: Risks to Health and Descriptions/Examples for Intracompartmental Pressure Monitors

Identified Risk	Description/Examples
Adverse tissue reaction	This risk can result from the use of device materials that are not biocompatible for patient contacting components of the device.
Device malfunction	This risk can result from mechanical, electrical, or software malfunctions, or use error (e.g., failure to adequately clean probe tips, incorrect placement of the device). This risk can lead to inaccurate diagnosis or delayed diagnosis, both of which could lead to a delay in treatment and a worsening of the condition (compartment syndrome). The risk could also lead to inappropriate therapy due to inaccurate measurement (e.g., false negative)
Electrical shock or burn	Electrical malfunction of the device may result in electrical shock or burns to the patient or user.
Interference with other devices	This risk can cause the device or other electrical devices to perform incorrectly which could lead to patient injury.
Infection	This risk can result from the use of a device whose sterility has been compromised. In addition, some components are provided non-sterile and/or are reusable, and failure to adequately clean and resterilize these components can also lead to infection.

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

5. Literature Review

5.1 Results

The American Academy of Orthopaedic Surgeons (AAOS), and the Major Extremity Trauma and Rehabilitation Consortium, with input from representatives from the Orthopaedic Trauma Association, the Society of Military Orthopaedic Surgeons, representatives from San Antonio Military Health System, and the U.S. Air Force Critical Care Air Transport Team, recently published their clinical practice guideline (CPG), Management of Acute Compartment Syndrome (ACS). This CPG was approved by the AAOS Board of Directors and has been officially endorsed by the American College of Surgeons and the American Orthopaedic

Foot & Ankle Society. To create the ACS CPG, over 3,600 abstracts and more than 480 full-text articles were reviewed to develop 15 recommendations supported by publications meeting stringent inclusion criteria. The purpose of this CPG is to diagnose and treat acute compartment syndrome based on current best evidence.

This summary notes that, while physical examination and clinical findings are the primary method for diagnosing acute compartment syndrome, measurement of intracompartmental pressure is a well-established method for diagnosing acute compartment syndrome and the best evidence available suggests repetitive compartment pressure monitoring as one of the most reliable adjuncts to diagnosis. In alert and responsive patients, relying solely on pressure readings should be avoided: clinical suspicion and clinical exam must factor into diagnosis as well. However, in obtunded patients the working group found no evidence regarding the utility of the clinical examination in diagnosing acute compartment syndrome. Therefore, the working group's consensus was that repeated or continuous pressure-based methods of diagnosis be used. Furthermore, the group found that in all studies where a differential pressure of 30 mmHg was used as a cutoff, pressure monitoring showed good sensitivity and/or specificity, indicating that, when combined with clinical symptoms, pressure monitoring can be useful in ruling out compartment syndrome.

Intracompartmental pressure monitoring was evaluated in one article (McQueen et al., 2013) and determined to have a 94% sensitivity for acute compartment syndrome, a 98% specificity, a positive predictive value of 93%, and an estimated negative predictive value of 99%. Of 979 monitored patients, 6 of 152 patients who underwent fasciotomy did not demonstrate intraoperative signs of compartment syndrome (false positives). Five patients underwent fasciotomy based on clinical findings despite negative pressure readings and all demonstrated intraoperative signs of compartment syndrome (false negatives). The authors concluded that the estimated sensitivity and specificity of continuous intracompartmental pressure monitoring for the diagnosis of acute compartment syndrome following tibial diaphyseal fracture are high; and continuous intracompartmental pressure monitoring should be considered for patients at risk for acute compartment syndrome.

One study (Boody et al., 2005) compared the reliability of various available pressure monitors (Stryker Intracompartmental Pressure Monitor System, arterial line manometer, Whiteside apparatus) and found the arterial line manometer with slit catheter to show the best correlation, while the Stryker system with the side-port needle demonstrated the least constant bias, and the Whitesides apparatus showed the worst correlation.

The objective of another article (Collinge et al., 2010) was to compare three commonly used methods and devices developed for measurement of intracompartmental pressure in injured limbs. Analysis of compartment

pressure data was collected using 1) a solid-state transducer intracompartmental catheter; 2) an electronic transducer-tipped catheter; and 3) a modification of Whitesides' needle manometer technique using a straight 18-gauge needle, arterial line transducer, and central venous pressure monitor. Intracompartmental pressure was measured by each method in 97 muscle compartments in 31 injured limbs of 26 trauma patients suspected to have a compartment syndrome. The authors conclude that the methods were similar but not completely reliable for measuring intracompartmental pressure in trauma patients. Although all methods appeared useful as aids in diagnosis of compartment syndrome, intracompartmental pressure data, especially single readings, must be interpreted in view of clinical findings.

A cadaver study attempted to evaluate physician performance in pressure measurement. 31% used correct technique, 39% were suboptimal in technique, and 30% were performed with significant deficiencies. Accuracy decreased as technical errors increased. Proper use improved accuracy, but even with proper technique, 40% of the measurements were >5 mm Hg from the actual pressure. Study authors commented that variations in use of a commercially available pressure monitors exist, and errors are common. The study concluded that regular review and education in the use of the devices should be a routine requirement to eliminate learning curve effects (Large et al., 2015).

The general guideline taught to most surgeons is that if compartment syndrome is suspected, fasciotomies should be performed as soon as possible. As stated in one article: “We believe that awareness of the possibility of acute compartment syndrome among nursing and medical staff is the most important factor contributing to an early diagnosis. Knowing that specific groups of patients are at risk should heighten awareness of the condition.” (McQueen et al., 2000). In other words, intracompartmental pressure monitoring is considered an adjunct to diagnosing rather than the major determinant. Clinical suspicion is preeminent.

In one publication of 109 tibial fracture patients, continuous pressure monitoring provided no significant benefit over careful clinical monitoring alone, in regard to both clinical outcomes and in the time delay from injury to fasciotomy (Al-Dadah et al., 2008). The fasciotomy rate for continuous monitoring vs. clinical monitoring was 15.6% vs. 14.7%. Time delay from injury to fasciotomy was 22 hours in the pressure monitored group and 23 hours in the clinically monitored group. Continuous compartment pressure monitoring did not increase the rate of unnecessary fasciotomies.

A publication by Pharaon et al., 2018, investigated management of low extremity trauma. The authors suggests that extremity compartment syndrome should be suspected in all critically-injured patients with or without fractures and that low threshold for compartment pressure measurements or empiric fasciotomy be maintained. While diagnosis can be made with physical exams alone when the patient is alert and responsive, Pharaon further notes that a handheld device such

as the Stryker Intracompartmental Pressure Monitor System can be a reliable aid when used appropriately.

5.2 Overall Literature Review Conclusions

Available literature demonstrates that intracompartmental pressure monitoring devices serve as a useful aid in the diagnosis of compartment syndrome. The literature further documents the primary importance of clinical evaluation, the adjunct nature of intracompartmental pressure monitoring devices, the greater importance of pressure monitoring in the obtunded patient, and the variations in devices and usage that can affect pressure monitoring results, which highlights the need for adequate directions for use in product labeling. Based on review of this published literature, these devices present a low risk due to the adjunct nature of the devices and the degree of physician experience and judgement that is involved when diagnosing compartment syndrome and deciding whether to perform a fasciotomy. Due to the time sensitive nature and potential morbidity of a compartmental syndrome injury, the literature indicates that the probable benefits to health from use of the device for the specific indications outweigh the probable risks (reasonable assurance of safety), and on that the device will provide clinically significant results in a significant portion of the target population (reasonable assurance of effectiveness). The MDR search reported below confirms these observations.

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: Intracompartmental Pressure Monitors

Individual MDRs for intracompartmental pressure monitors 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.

A total of 16 MDRs were reported from January 1987 through December 2019 for the LXC product code in the MAUDE database. The majority of reports involved error/malfunction messages due to failure of the probes to detect, or correctly detect, intracompartmental pressures. Three of these 'malfunctions' were deemed to be use error due to failure to adequately clean probe tips prior to reuse.

Six MDRs were reported from 1992 to 1996 for the LXC product code in the FDA's Medical Device Reporting (MDR) database. Reports were regarding inaccurate readings resulting from one manufacturer's device (Stryker). The firm initiated a recall based on findings of an air leak in the subject device.

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: Intracompartmental Pressure Monitors

One class 2 recall has been identified in the Medical Recall Database with the product code LXC. A Stryker brand Intra-Compartmental (STIC) Pressure Monitor, Model 295-001-000, was recalled in 2005 as the pressure indicated may have been inaccurate, and this inaccuracy may not have been detectable by the user.

As noted in the Section 6.2, above, one other recall was noted in 1993, prior to initiation of the November 2002 Medical Device Recalls database. The sponsor,

Stryker, noted that a recall was conducted based on findings of an air leak in their device that led to erroneously low readings.

8. Summary

Considering the information available, the Panel will be asked to comment on whether intracompartmental pressure monitors under product codes "LXC":

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 intracompartmental pressure

monitors. 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 3: Summary of Risks to Health and Proposed Special Controls for Intracompartmental Pressure Monitors

Identified Risk	Recommended Mitigation Measure
Adverse tissue reaction	• Biocompatibility evaluation • Labeling
Device malfunction	• Non-clinical performance evaluation – (mechanical testing; software verification, validation, and hazard analysis) • Labeling
Electrical shock or burn	• Non-clinical performance evaluation – (electrical testing) • Labeling
Interference with other devices	• Non-clinical performance evaluation – (electromagnetic compatibility (EMC) testing) • Labeling
Infection	• Sterilization validation • Packaging validation • Cleaning validation • Labeling

The Panel will be asked whether this list is a complete and accurate list of the risks to health presented for intracompartmental pressure monitors and whether any other risks should be included in the overall risk assessment of the device type.

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 intracompartmental pressure monitors under product code "LXC":

1. Patient contacting components of the device must be demonstrated to be biocompatible.

2. Non-clinical performance evaluation must demonstrate that the device performs as intended under anticipated conditions of use. The following must be conducted:

i) an assessment of the mechanical output specifications including testing to validate the accuracy of the probe pressure measurement, if applicable
ii) mechanical safety testing to validate safeguards related to the pressure aspects of the device
iii) electrical safety, thermal safety, and electromagnetic compatibility (EMC) of all electrical components of the device
iv) software verification, validation, and hazard analysis.

3. Validation testing must demonstrate the sterility of the final packaged device.

4. Validation of reprocessing instructions to demonstrate reusable or non-sterile components of the device can be adequately cleaned and resterilized.

5. The labeling for the device must include the following:

i) importance of adequately cleaning probe tips
ii) importance of accurate placement of the device
iii) validated reprocessing instructions (cleaning, sterilization) for non-sterile and/or reusable devices
iv) instructions for proper handling of electrical components.

If the Panel believes that Class II is appropriate for intracompartmental pressure monitors under product code "LXC," 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 intracompartmental pressure monitors indicated for use for the measurement of intracompartmental pressures in patients with known or suspected cases of compartment syndrome or conditions that may lead to increasing levels of intracompartmental pressure be regulated as Class II devices.

888.1700. Intracompartmental pressure monitor.

(a) *Identification.*
An intracompartmental pressure monitor is a device intended for the monitoring of compartmental pressures to aid in the diagnosis of compartment syndrome.

Devices may also include a vacuum pump to remove fluid for analysis.

(b) *Classification.*

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

1. Patient contacting components of the device must be demonstrated to be biocompatible.

2. Non-clinical performance evaluation must demonstrate that the device performs as intended under anticipated conditions of use. The following must be conducted:

   i) an assessment of the mechanical output specifications including testing to validate the accuracy of the probe pressure measurement, if applicable
   ii) mechanical safety testing to validate safeguards related to the pressure aspects of the device
   iii) electrical safety, thermal safety, and electromagnetic compatibility (EMC) of all electrical components of the device
   iv) software verification, validation, and hazard analysis

3. Validation testing must demonstrate the sterility of the final packaged device.

4. Validation of reprocessing instructions to demonstrate the device can be adequately cleaned and resterilized.

5. The labeling for the device must include the following:

   i) importance of adequately cleaning probe tips
   ii) importance of accurate placement of the device
   iii) validated reprocessing instructions (cleaning, sterilization) for nonsterile and/or reusable devices
   iv) instructions for proper handling of electrical components

Based on the available scientific evidence, the FDA will ask the Panel for their recommendation on the appropriate classification of intracompartmental pressure monitors under product code "LXC."

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