Classification of Intracompartmental Pressure Monitor Devices Under Product Code LXC

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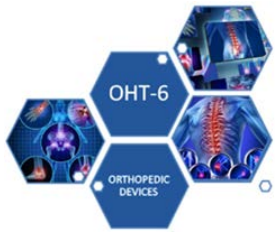

Outline

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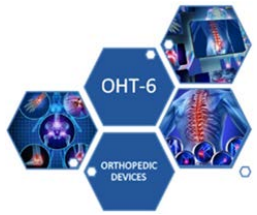
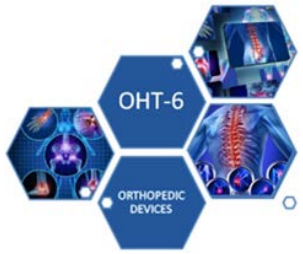


Intracompartmental Pressure Monitor Devices (LXC)

- Intended Use: Monitoring of intracompartmental pressures to aid in the diagnosis of compartment syndrome.
- Product code LXC: “Monitor, Pressure,Intracompartmental”.
- Currently unclassified i.e. no regulation associated with the product code.



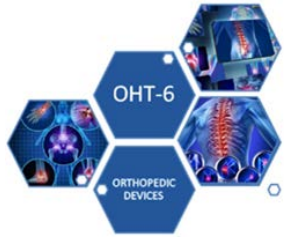
Device Description

- The cleared devices use one of two methods to measure pressure.

    1) Slit catheter: fluid-filled catheter inserted in the compartment and measures compartment pressure with an arterial line transducer. The catheter may be in-dwelling, allowing for continuous monitoring.

    2) Syringe-based manometer: measures the resistance present when a small volume of saline solution is injected into the compartment - used for intermittent measurements.

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

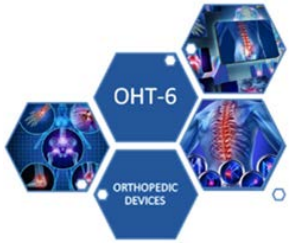


Indications for Use

- 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.

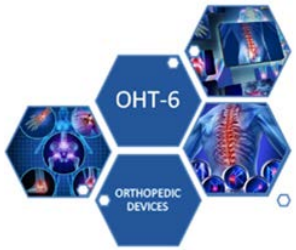
- The measured intracompartmental pressures can be used as an aid in the diagnosis of compartment syndrome.



Regulatory History

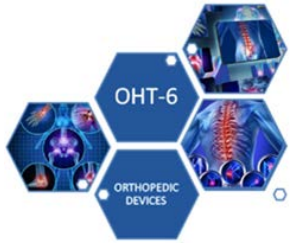
Table 1: 510(k) clearances for intracompartmental pressure monitors under product code “LXC”

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.



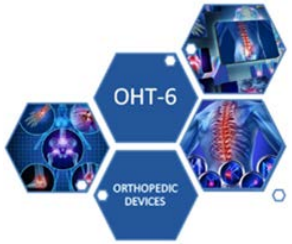
Regulatory Pathway

- Pre-amendment, i.e., marketed prior to May 1976
- Unclassified when marketed
- 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.



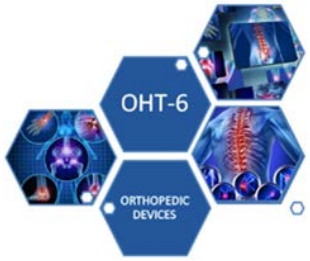
Clinical Background

- Compartment syndrome: excessive soft tissue pressure within enclosed and unyielding fascial envelopes
- Most common etiology: Trauma
- Increased compartment pressure threatens vascular occlusion, reduced blood flow, and tissue (muscle) necrosis
- Possible sequelae of untreated compartment syndrome: severe muscle necrosis, permanent neurovascular injury, marked extremity damage, may lead to amputation.
- Potential for renal damage due to rhabdomyolysis and myoglobinuria.



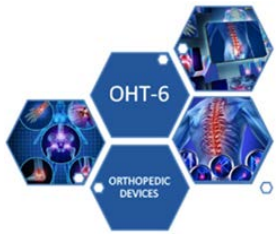
Clinical Background (Cont'd)

- Common Etiologies of Compartment Syndrome
  - Fracture, tibia most common
    - Acutely due to bleeding into a confined fascial compartment
    - Secondary to subsequent edema
    - As a result of fracture management e.g. casts, splints, ace wraps, etc.
  - Injuries other than fractures
    - Overly tight bandaging
    - Prolonged compression of a limb during a period of unconsciousness
    - Surgery to blood vessels of an arm or leg
    - Vascular injuries
    - A blood clot in a blood vessel in an arm or leg
    - Crush injuries in cognitively impaired (e.g. opioid overdose)



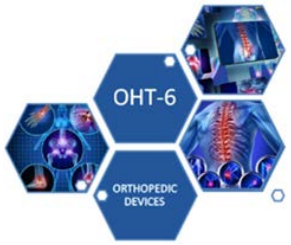
Current Approach to Treatment

- Diagnosis: Scrupulous attention to physical findings.
- Response to increasing pain, decreasing pulses (not always present), pain on passive stretch, tightness of compartment to palpation should elicit an immediate response.
- Non-surgical treatment modalities: 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. These are rarely effective.
- Surgical treatment: Emergency fasciotomies to release compartment pressure (30 mm Hg compartment pressure often considered a cutoff)



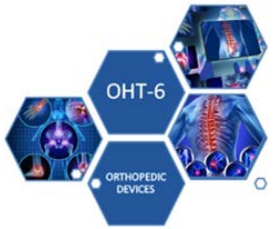
Literature Review

- 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 “LXC.”
- Literature searches were performed in two electronic databases (MEDLINE and Embase)
- The searches were limited to publications in English and yielded 135 initial literature references. After duplicate articles were removed, the literature search of the above electronic databases yielded 59 literature references.
- A total of 8 published literature references were determined to be relevant to the safety and efficacy of intracompartmental pressure monitors.



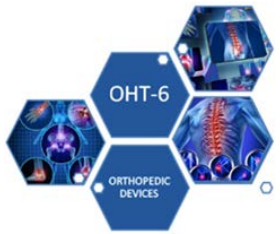
Literature Review

- Summary of Clinical Practice Guideline (CPG), Management of Acute Compartment Syndrome from the American Academy of Orthopaedic Surgeons
  - 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.



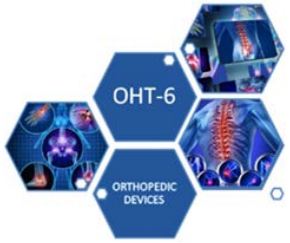
Literature Review

- Recommendation from CPG (cont.)
  - In patients with a more depressed level of consciousness (obtunded) the working group found no evidence regarding the utility of the clinical examination alone in diagnosing acute compartment syndrome
  - Consensus was that repeated or continuous pressure-based methods of diagnosis be used.
  - 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.



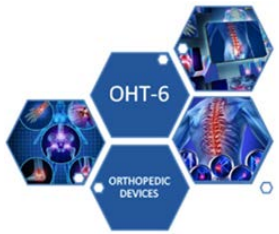
Literature Review

- McQueen et al., 2013
  - 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%. (McQueen et al. 2013)
  - Study 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.



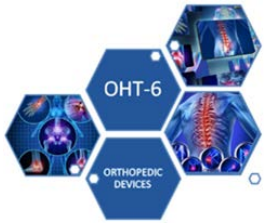
Literature Review

- Boody et al., 2005
  - Compared the reliability of three available pressure monitors (Stryker Intracompartmental Pressure Monitor System, arterial line manometer, Whiteside apparatus) when used with straight needles, side-port needles, and slit-catheters, to a known pressure.
  - Arterial line manometer with slit catheter showed 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.



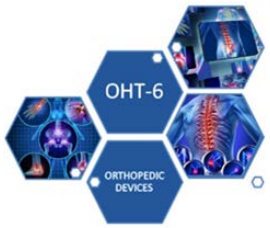
Literature Review

- Collinge et al., 2010
  - Compared three commonly used methods and devices developed for measurement of intracompartmental pressure in injured limbs.
    - 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.
  - 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.



Literature Review

- Large et al., 2015
  - A cadaver study evaluated 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.
  - Noted that variations in use of a commercially available pressure monitor exist, and errors are common.
  - Study conclusion: regular review and education in the use of the devices should be a routine requirement to eliminate learning curve effects.



Literature Review

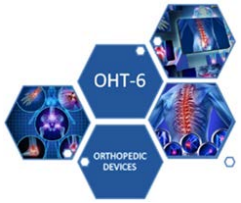
- McQueen et al., 2000
  - General guideline taught to most surgeons is that if compartment syndrome is suspected fasciotomies should be performed as soon as possible.
  - Awareness of the possibility of acute compartment syndrome among nursing and medical staff is the most important factor contributing to an early diagnosis.
  - Knowing that specific groups of patients are at risk should heighten awareness of the condition.
  - Intracompartmental pressure monitoring is considered an *adjunct* to diagnosing rather than the major determinant.

Literature Review

- Al-Dadah et al., 2008
  - This study compared continuous monitoring vs. clinical monitoring.
  - 109 tibial fracture patients continuous pressure monitoring provided no benefit over careful clinical monitoring in regard to clinical outcome, and delay from injury to fasciotomy. 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.

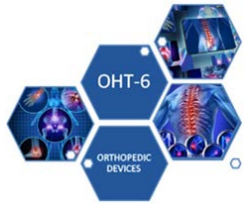
Literature Review

- Phareon et al., 2018
  - Investigated management of low extremity trauma.
  - Authors suggest that extremity compartment syndrome should be suspected in all critically injured patients with or without fractures and that a low threshold for compartment pressure measurements or empiric fasciotomy be maintained.
  - Authors concluded that while diagnosis can be made with physical exams alone when the patient is alert and responsive, a handheld device such as an Intracompartmental Pressure Monitor System can be used and be reliable when used appropriately.



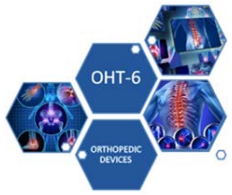
Medical Device Reports

- Medical Device Reporting (MDR): the mechanism for the FDA to receive significant medical device adverse events from:
  - mandatory reporters (manufacturers, importers and user facilities)
  - voluntary reporters (health care professionals, patients, consumers)



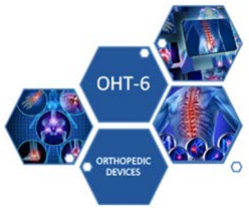
Medical Device Reports

- MDR reports 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, including:
    - rare, serious, or unexpected adverse events
    - adverse events that occur during long-term device use
    - adverse events associated with vulnerable populations
    - off-label use
    - user error



Medical Device Reports

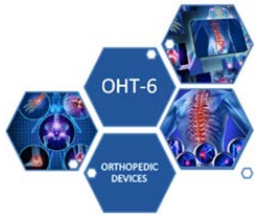
- Limitations
  - Under reporting of events
  - Potential submission of incomplete, inaccurate, untimely, unverified, or biased data
  - Incidence or prevalence of an event cannot be determined from this reporting system alone
  - Confirming whether a device actually caused a specific event can be difficult based solely on information provided in a given report
  - MAUDE data does not represent all known safety information for a reported medical device



Medical Device Reports - Summary

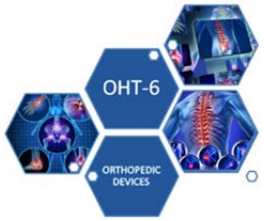
- Sixteen 16 MDR's reported from 1/1/1987 to 12/31/19 for the LXC product code in the MAUDE database. The majority of reports involved a malfunction of the probes to detect, or correctly detect, intracompartmental pressures, and error messages. Three 'malfunctions' were deemed to be user error due to failure to adequately clean probe tips prior to reuse.

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



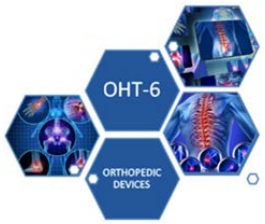
Risks and Mitigations

- Manufacturer and User facility Device Experience (MAUDE)/MDR databases (up to 2020)
- Information available to FDA regarding cleared devices
- Review of published literature



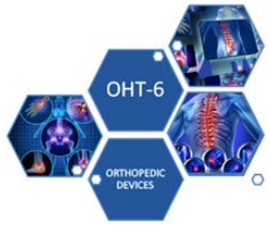
Risks

- Adverse tissue reaction - to patient-contacting components of the device.
- Device malfunction - leading to inaccurate diagnosis or delayed diagnosis, both of which could lead to a delay in treatment and a worsening of the condition (compartment syndrome).
- 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 – electrical interference can cause the device or other electrical devices to perform incorrectly which could lead to patient injury.
- Infection – can result from compromised sterile packaging, or failure to clean and re-sterilize non-sterile and/or reusable components.



Mitigations

Identified Risk	Recommended Mitigation Measures
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



Proposed Classification

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)

Proposed Special Controls

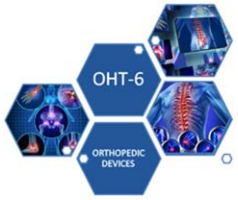
888.1700. Intracompartmental pressure monitor

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

We propose the following Special Controls for these devices:

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



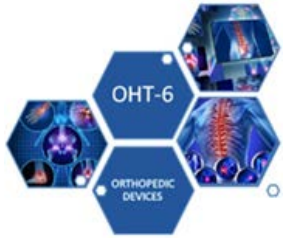
Proposed Special Controls

Special Controls (cont'd):

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

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

5. The labeling for the device must include the following:
   - importance of adequately cleaning probe tips
   - importance of accurate placement of the device
   - validated reprocessing instructions (cleaning, sterilization) for nonsterile and/or reusable devices
   - instructions for proper handling of electrical components



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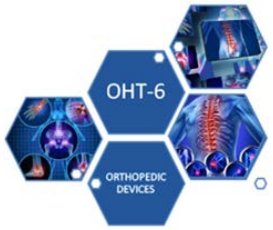
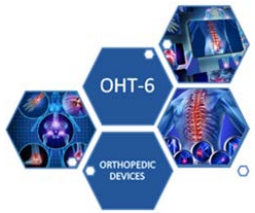


Questions to Panel

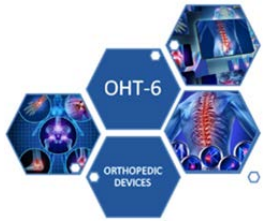
LXC



Question 1 to Panel

Please comment on whether you agree with inclusion of all of the risks in the overall risk assessment of the intracompartmental pressure monitor devices under product code “LXC”.

In addition, please comment on whether you believe that any additional risks should be included in the overall risk assessment of these intracompartmental pressure monitor devices.

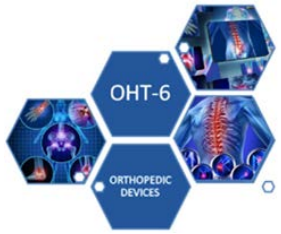


Question 2 to Panel

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

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

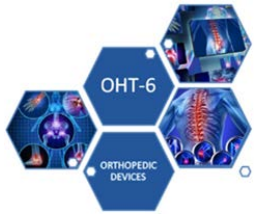


Question 2 to Panel (Cont'd)

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

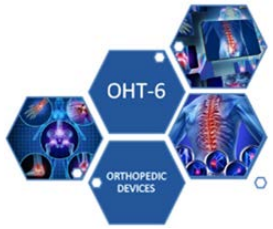
4. Validation of reprocessing instructions to demonstrate reusable or non-sterile components of the device can be adequately cleaned and resterilized.

5. The labeling for the device must include the following:
   - importance of adequately cleaning probe tips
   - importance of accurate placement of the device
   - validated reprocessing instructions (cleaning, sterilization) for nonsterile and/or reusable devices
   - instructions for proper handling of electrical components



Question 3 to Panel

Please discuss whether you agree with FDA's proposed classification of Class II with special controls for intracompartmental pressure monitors. If you do not agree with FDA's proposed classification, please provide your rationale for recommending a different classification.



End of Panel Questions for Product Code “LXC”