Classification of Intracompartmental Pressure Monitors
FDA Questions

Orthopaedic and Rehabilitation Devices Panel of Medical Devices Advisory Committee
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1. FDA has identified the following risks to health 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.

Please comment on whether you agree with inclusion of all of the risks in the overall risk assessment of intracompartmental pressure monitors 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 monitors.

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 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.

Risk/mitigation recommendations for intracompartmental pressure monitors under product code "LXC"

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

Please discuss whether the identified special controls for intracompartmental pressure monitors 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:
    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.

3. **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.**