Classification of Plunger-Like Joint Manipulators
FDA Questions

Neurological Devices Panel of the Medical Devices Advisory Committee June 3-4, 2021

1. FDA has identified the following risks to health for plunger-like joint manipulators:

Identified Risk	**Description/Examples**
Adverse tissue reaction	This can result from use of device materials that are not biocompatible.
Electric shock or burn	This can result from electrical failure or malfunction.
Pain	This risk could be due to a mechanical, electrical or software malfunction causing device failure. Types of pain include neck pain, radiating pain, and mid-back pain.
Discomfort	This risk can be caused by a mechanical, electrical, or software malfunction causing device failure. Types of discomfort include headache, fatigue, dizziness, stiffness, mild soreness, arm weakness, and arm numbness.
Tissue Injury	This risk could be due to a mechanical, electrical or software malfunction causing device failure. An example of tissue injury includes bruising from excessive force or pressure.

Please comment on whether you agree with inclusion of all the risks in the overall risk assessment of plunger-like joint manipulators under product code "LXM". In addition, please comment on whether you believe that any additional risks should be included in the overall risk assessment of these plunger-like joint manipulators.

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 plunger-like joint manipulators. 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 plunger-like joint manipulators under product code "LXM"

Identified Risk	**Recommended Mitigation Measure**
Adverse tissue reaction	• Biocompatibility evaluation
Electric shock or burn	• Electromagnetic compatibility (EMC) testing • Electrical, mechanical, and thermal safety testing
Pain	• Electromagnetic compatibility (EMC) testing • Electrical, mechanical, and thermal safety testing • Non-clinical performance testing • Software verification, validation, and hazard analysis • Labeling
Discomfort	• Electromagnetic compatibility (EMC) testing • Electrical, mechanical, and thermal safety testing • Non-clinical performance testing • Software verification, validation, and hazard analysis • Labeling

Identified Risk	Recommended Mitigation Measure
Tissue injury	• Electromagnetic compatibility (EMC) testing • Electrical, mechanical, and thermal safety testing • Non-clinical performance testing • Software verification, validation, and hazard analysis • Labeling

Please discuss whether the identified special controls for plunger-like joint manipulators appropriately mitigate the identified risks to health and whether additional or different special controls are recommended:

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

2. Electromagnetic compatibility and electrical, mechanical, and thermal safety testing must be performed.

3. Non-clinical performance testing must characterize the thrust force applied to the patient.

4. Software verification, validation, and hazard analysis must be performed.

5. Labeling must include:

   (i) A warning that the device could cause pain, including neck pain, radiating pain, mid-back pain and tissue injury.
   (ii) A warning that the device could cause discomfort, including headache, fatigue, dizziness, stiffness, mild soreness, arm weakness, and arm numbness.

3. **Please discuss whether you agree with FDA's proposed classification of Class II with special controls for plunger-like joint manipulators devices. If you do not agree with FDA's proposed classification, please provide your rationale for recommending a different classification.**