Classification of Plunger-Like Joint Manipulators Under Product Code "LXM"

Presenter
Kaitlin Olsen, M.S.
Division of Neuromodulation and Physical Medicine Devices
Office of Health Technology 5-Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
Food and Drug Administration

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Device Description

- Most cleared plunger-like joint manipulators are handheld electromechanical instruments (either AC or battery powered). The power generated charges a solenoid, which then generates a thrust force delivered to the patient via a plunger attached to a metal stylus.
- Other plunger-like joint manipulators comprise of an actuator/electronic control and positioning stand.
- The patient is positioned on the table and the chiropractor positions the stylus against the desired region of the vertebra.

Indications for Use

- The IFU statements for plunger-liked joint manipulators refer to chiropractic adjustment or manipulation without identifying a specific disease or condition to be treated. Almost all specify targeting vertebrae or joints, although ligaments and soft tissues are also addressed.
- Devices have been cleared for either over-the-counter (OTC) use or for prescription (Rx) use.

Regulatory History

- 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.
- To date, FDA has cleared 30 plunger-like joint manipulators under product code LXM.

Clinical Background

- Spinal manipulation is a form of manual therapy that involves the deliberate high-velocity, passive movement of a joint in the spine or periphery and may also be referred to as spinal adjustment.
- Goals of manipulation include symptom reduction through passive movement of the affected and adjacent areas.
- Manipulation or adjustments can be considered appropriate treatments for some types of musculoskeletal pain in the neck, back, shoulders and in some headache syndromes.
- Acute and chronic musculoskeletal pain can be the result of various underlying problems including muscle strain, sprain, overuse syndromes, tendinopathies and arthritis.

Clinical Background

- Alternative treatment options for musculoskeletal pain
  - Manual spinal manipulation
  - Heating or cooling
  - Bracing
  - Therapeutic exercise
  - Topical analgesics
  - Injection of local anesthetics
  - Oral medications: non-steroidal anti-inflammatory medications, acetaminophen, muscle relaxants including methocarbamol, cyclobenzaprine, carisoprodol and metaxalone.

Literature Review

- A systematic literature review was conducted in an effort to gather any published information regarding the safety and effectiveness of plunger-like joint manipulators under product code “LXM.”
- Literature searches were conducted to identify any relevant articles published between April 27, 2010 and December 31, 2020.
- The searches were limited to publications in English and excluded conference proceedings and abstracts.
- The searches yielded 561 initial literature references. After duplicate articles were removed, the literature search of the above electronic databases yielded 548 literature references.
- A total of 7 published literature references were determined to be relevant to the safety and/or effectiveness of plunger-like joint manipulators.

Literature Review – Safety Assessment

Neck Pain (5 articles)

- Three of the 5 articles reported adverse events
- Reported adverse events include:
  - Neck pain
  - Radiating pain
  - Arm weakness
  - Arm numbness
  - Headache
  - Fatigue
  - Dizziness
  - Mid-back pain
  - Stiffness, mild soreness, or pain during neck movement

Low Back Pain (2 articles)

- No articles reported adverse events

Literature Review – Effectiveness Assessment

Neck Pain (5 articles)

- Four of five studies reported a statistically and/or clinically significant reduction in pain from baseline ($p < 0.05$).

Low Back Pain (2 articles)

- For the treatment of low back pain, the plunger-like joint manipulator did not provide statistically and/or clinically significant improvement in pain or disability outcomes compared to manual manipulation or usual medical care.

Literature Review – Summation

- The literature reports minimal safety risks with three of the seven studies reporting mild and transient adverse events.
- Four of five studies reported statistically and/or clinically significant reduction in neck pain. The remaining two studies did not demonstrate statistically or clinically significant improvement in pain when evaluating the effectiveness of plunger-like joint manipulators in the treatment of low back pain.
- No studies evaluated plunger-like joint manipulators for indications other than spinal manipulation (for treatment of neck pain or back pain), though these devices are also cleared for other uses such as extremity manipulation and spinal/extremities mobilization.

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

- MAUDE (Manufacturer And User Facility Device Experience) Database reviewed for product code “LXM” from April 1, 1988 through December 31, 2020:
  - 5 relevant MDRs were identified: injury (N= 4) and malfunction (N= 1).
    - The injury reports noted an unspecified injury (N=2), pain and hearing loss (N= 1), and pain, paralysis, and dyspnea (N=1).
    - The malfunction report was a manufacturer report that noted failed repair of the device and no known patient involvement.

Recall History

- 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 (resulting in the posting date) may occur after the firm recalling the medical device product conducts and communicates with its customers about the recall.

Recall History

- A review of the database found only one recall for devices cleared under product code “LXM”
  - One class II recall was identified in the Medical Recall Database. A Model 8000 Atlas C-1 Orthogonal Adjusting Instrument was recalled in 2013 because the firm was marketing their device without marketing authorization.

Risks

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.

Risk and Mitigations

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

Proposed Classification

882.5055. Plunger-like joint manipulator.

(a) *Identification.* A plunger-like joint manipulator is an electromechanical device intended to perform chiropractic adjustment or manipulation of the spinal column and/or extremities. Joint manipulation is achieved through a thrust force delivered to the patient via a plunger attached to a metal stylus, positioned over the desired region of the vertebra.

(b) *Classification.*

Class II (special controls).

Proposed Special Controls

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.

Thank You

Questions to Panel - LXM

Question 1 to Panel

- 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.

Question 1 to Panel

- 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.

Question 2 to Panel

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
- 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.

Question 2 to Panel

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
    - 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
    - does not present a potential unreasonable risk of illness or injury.

Question 2 to Panel

FDA believes general controls alone 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 cleared under product code “LXM.”

Question 2 to Panel

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.

Question 2 to Panel

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

Question 2 to Panel

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.

Proposed Special Controls:

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.

Question 3 to Panel

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.

End of Panel Questions for Product Code “LXM”