Classification of Cemented Total First Metatarsophalangeal (MTP) Replacement Devices
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 cemented total first metatarsophalangeal (MTP) replacement devices based upon literature findings, the Manufacturer and User facility Device Experience (MAUDE) database, and the risks associated with total joint arthroplasty devices; however, this list may not be exhaustive:

Identified Potential Risk	Description/Example
1. Failure at the bone/implant interface (e.g., Lack of hallux purchase; Implant migration; Loosening of the prosthesis)	Components may loosen, migrate, or disengage from the bone; this may result in pain, injury, or loss of correction.
2. Fracturing of the metatarsal head or base of the proximal phalanx during implantation	During the surgical procedure there is a risk of fracturing of the metatarsal head or base of the proximal phalanx when implanting the device which may cause prolonged surgery times, pain, and loss of correction.
3. Osteolysis or heterotopic ossification around the implant system	There is a risk of osteolysis or heterotopic ossification around the implant system which may lead to pain, implant failure, loss of function, or loss of correction.
4. Sesamoid pathology	There is a risk of sesamoid pathology (e.g., subluxation, arthrosis of the metatarso-sesamoid junction) associated with total MTP joint replacement which may cause pain and loss of function.
5. Recurrence of the hallux deformity	There is a risk that the hallux deformity may recur due to user error, disease state, or patient non-compliance. This may result in pain, loss of function, or additional procedures.
6. Painful/limited first MTP joint range of motion	There is a risk of pain and stiffness associated with MTP joint replacement which may limit the range of motion.
7. Implant breakage or disassociation of components	Components may fracture, wear, or disassemble, resulting in mechanical or functional failure; this may result in pain, injury, or loss of correction
8. Infection	There is a risk of infection in the wound or around the implant. This may cause pain, stiffness, swelling, fever, or fatigue.
9. Dislocation/Subluxation	Components may partially or fully dislocate leading to pain, loss of function, or loss of correction.

10. Use Error	Risks of use error may include difficulty or inability to implant the device components or incorrect placement of the device. This may lead to mechanical or functional failure and result in pain or injury.
11. Adverse Tissue Reaction	Device material(s) may elicit adverse tissue reactions, such as foreign body response, metal allergy, and metal toxicity
12. MR induced migration and heating and image artifact	Some of the materials used to manufacture cemented total first MTP joint replacements may create a risk of migration and heating in the MR environment which may lead to pain, injury, and loss of function. There is also a risk of image distortion which may affect the ability to image the surrounding area for new pathologies.
13. Multiple secondary surgeries as sequelae of device removal	There is risk of multiple secondary surgeries as revision of arthroplasty is challenging to manage as significant bone loss in introduced by the initial procedure.

Please comment on whether you agree with inclusion of all of the risks in the overall risk assessment of cemented total first MTP joint implants under product code "LZJ." In addition, please comment on whether you believe that any additional risks should be included in the overall risk assessment of these cemented total first MTP joint implants.

2. The risk/mitigation table below outlines the identified risks to health and potential controls that FDA could apply to mitigate each identified risk. Please discuss each of these potential controls and whether it, either alone or in combination with others, adequately mitigates the identified risk(s).

Identified Risk	Potential Mitigation Measure
Failure at the bone/implant interface (e.g., lack of hallux purchase; implant migration; loosening of the prosthesis)	Design Characteristics Clinical Information* Labeling Non-clinical Performance Testing
Fracturing of the metatarsal head or base of the proximal phalanx during implantation	Design Characteristics Non-clinical Performance Testing Labeling
Osteolysis or heterotopic ossification around the implant system	Labeling Non-clinical Performance Testing
Sesamoid pathology	Labeling
Recurrence of the hallux deformity	Labeling
Painful/limited first MTP joint range of motion	Design Characteristics Labeling Non-clinical Performance Testing
Implant breakage or disassociation of components	Design Characteristics Non-clinical Performance Testing Labeling
Infection	Cleaning and Sterilization Validation

Identified Risk	Potential Mitigation Measure
Dislocation/Subluxation	Design Characteristics Non-clinical Performance Testing
User Error	Labeling Non-clinical Performance Testing
Adverse Tissue Reaction	Design Characteristics Biocompatibility Testing
MR induced migration and heating and image artifact	Labeling Non-clinical performance testing
Multiple secondary surgeries as sequelae of device removal	Labeling Clinical Information*

***** Clinical information may come from a variety of sources, premarket or post-market, including but not limited to, prospective or retrospective studies, literature, and real-world evidence sources (e.g., registries or electronic health records).

Please discuss whether the identified potential controls for cemented total first MTP joint implants appropriately mitigate the identified risks to health and whether additional or different controls are recommended.

In addition, please discuss the following in relation to the mitigation of the identified risks:

i. **The risks associated with multiple secondary surgeries are particularly significant and possibly long-lasting. Please discuss how the risk of multiple secondary surgeries should influence the selection of cemented total first MTP joint implant arthroplasty when considering the overall benefit and risk profile of the subject devices and comment on the recommended mitigations to address this risk.**

ii. **Given the apparently equivocal and low-quality data available in published literature, please comment on how the available evidence is used to determine the choice to use these devices in cemented total first MTP joint implant arthroplasty. As part of this discussion, please discuss the outcomes that provide clinically meaningful benefit and what types of evidence (such as clinical evidence) would be helpful to support mitigation of the identified risks.**

3. 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 cemented total first MTP joint implants.

Based upon the information presented in the panel package and today's discussion, please discuss whether you agree with FDA's proposed classification of Class II with special controls for cemented total first MTP joint implants. If you do not agree with FDA's proposed classification, please provide your rationale for recommending a different classification.