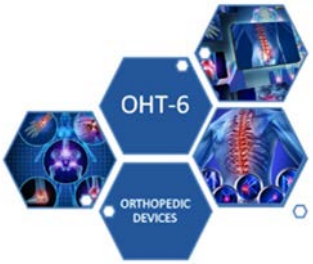

Classification of Cemented Total First Metatarsophalangeal Replacement Devices

Michael Owens, M.S., and Victoria Lilling, MD
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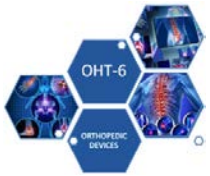
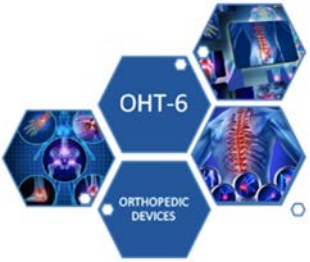
Office of Health Technology 6- Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
Food and Drug Administration

Orthopaedic and Rehabilitation Devices Panel Meeting
September 9, 2020



Outline

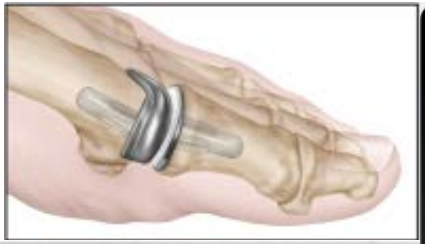
- Device Description
- Indications for Use
- Regulatory History
- Clinical Background
- Literature Review
- Medical Device Reports
- Risks to Health & Mitigations
- Classification
- FDA Questions

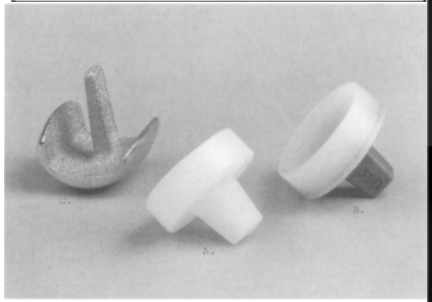


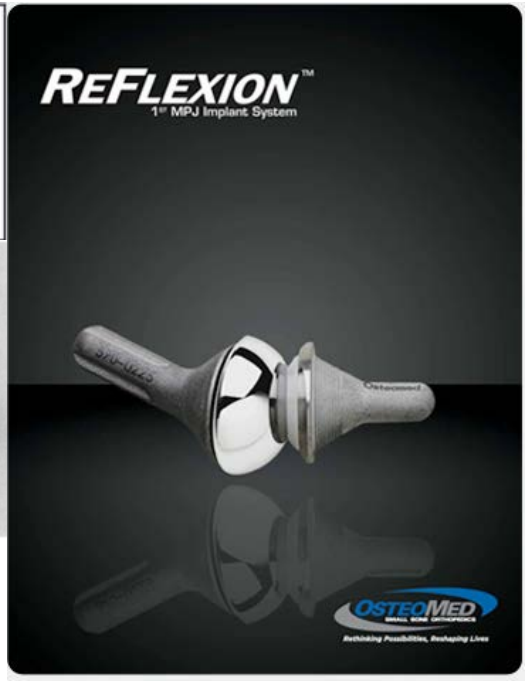
Device Description

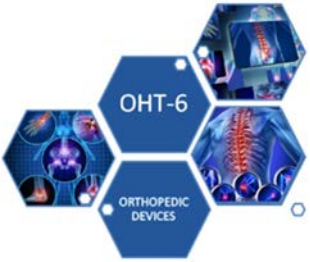
- A cemented total first MTP joint implant is a device intended to be implanted to replace the first MTP joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across the joint.
- This generic type of device includes prostheses that have a metatarsal component made of alloys, such as Cobalt-Chromium-Molybdenum, and a phalangeal component or components made of alloys, such as Ti-6Al-4V, and ultra-high molecular weight polyethylene. This generic device is limited to those prostheses intended for use with bone cement.

Device Description





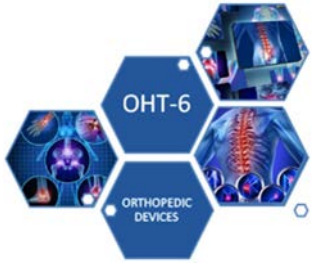




Indications for Use

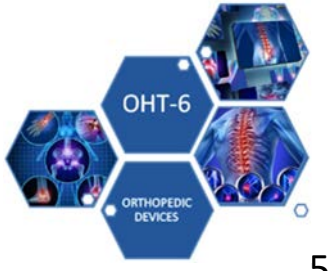
The Indications for Use (IFU) statement identifies the condition and patient population for which a device should be appropriately used. There is some minor variability in the indications for use for these products but representative indications for use for cemented total first MTP joint implants under product code “LZJ” are as follows:

- Intended for reconstruction of painful and/or severely disabled great toe joints. The device is intended for cemented use only. Indications include:
  - Painful degenerative metatarsophalangeal joint change
  - Hallux rigidus stage 3 and 4 (including rheumatoid and osteoarthritis causes of hallux rigidus)
  - Revisions after moderate proximal phalanx resection



Regulatory History

- The cemented total first MTP joint implant is a pre-amendment, unclassified device type. This means that this device type was marketed prior to the Medical Device Amendments of 1976 but was not classified by the original classification panels. 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 “LZJ.”



Regulatory History

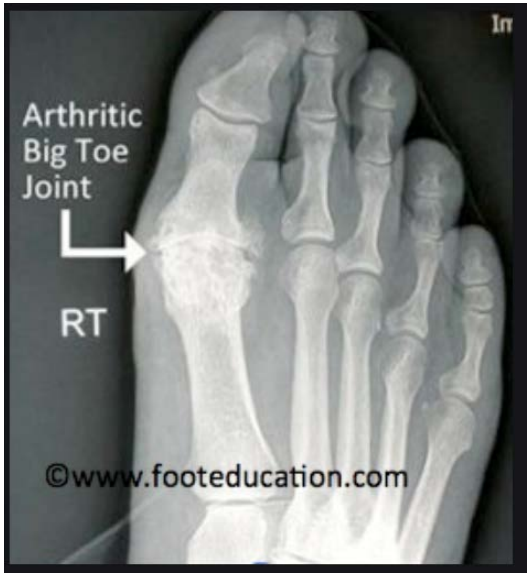
510(k) clearances for cemented total first MTP joint implants

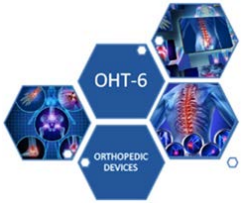
510(K) NUMBER	TRADE NAME	SPONSOR
K132496	ARTHROSURFACE TOEMOTION	ARTHROSURFACE, INC.
K102549	THE ASCENSION MOVEMENT GREAT TOE SYSTEM TOTAL ARTHROPLASTY	ASCENSION ORTHOPEDICS, INC.
K072251	MERETE TOEMOBILE ANATOMICAL GREAT TOE RESURFACING SYSTEM	MERETE MEDICAL GMBH
K950864	GTS GREAT TOE SYSTEM - (METATARSAL COMPONENT WITH POROUS COATING)	ACUMED INC.
K941650	TOTAL TOE SYSTEM II	BIOMET INC.
K924724	KINETIK GREAT TOE SYSTEM	KINETIKOS MEDICAL INC.
K922211	OSTEOMED GREAT TOE SYSTEM	OSTEOMED CORP.
K920446	TOTAL TOE SYSTEM	BIOMET INC.
K920667	GREAT TOE IMPLANT	ACUMED INC.
K911552	ANATOMIC TOE SYSTEM	ORTHOPAEDIC BIOSYSTEMS
K884561	KOENIG TOTAL TOE IMPLANT	DOW CORNING WRIGHT
K863528	DEPUY BICONDYLAR TOE PROSTHESIS	DEPUY, INC.
K860163	DEPUY BICONDYLAR TOE PROSTHESIS	DEPUY, INC.

Clinical Background

Disease Characteristics

- The integrity of the MTP joint may be compromised by a range of conditions such as:
  - Hallux Rigidus
  - Prior surgical treatment
- These conditions result in pain, loss of function, and decreased quality of life.



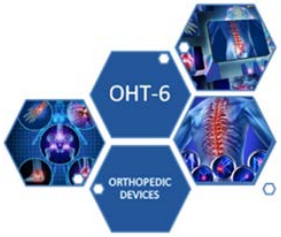


Clinical Background (Cont'd)

FDA

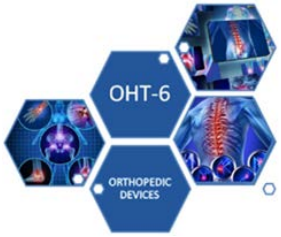
Currently Available Treatment

- Arthrodesis
- Arthroplasty
  - Four types of arthroplasty procedures:
    - Silastic (Silicon based): maintains length, dynamic spacer
    - Interposition Arthroplasty: joint sparing procedure; maintains joint
    - Metallic Hemiarthroplasties: replace one side of the MTP joint
    - Total Joint Replacement: replace the MTP joint



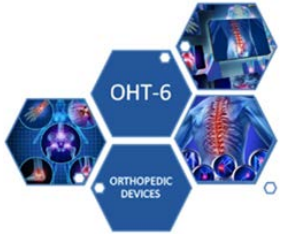
Literature Summary

- Of the articles that were reviewed in detail, only eight included summary clinical data on the primary use of total first MTP implants. All but one were Level IV case series.
- The review of published literature for total first MTP joint implants included a mix of cemented and uncemented experience.
- While positive results have been documented in literature, effectiveness for relief of pain or restoration of motion had mixed results. Some reports showed higher adverse event rates, mixed results, and notable revision rates due to pain and loosening.
- According to literature, revision of MTP joint implants are challenging to manage as significant bone loss is introduced by the initial procedure and places patients at risk for multiple secondary surgeries.



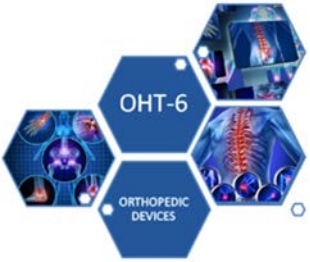
Literature Summary (Cont'd)

Given the apparently equivocal and low-quality data available in published literature, the Panel will be asked to comment on how 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, the Panel will be asked to explore 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.



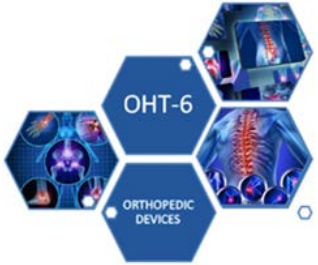
Medical Device Reports

- Medical Device Report (MDR) reporting: 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
    - use error

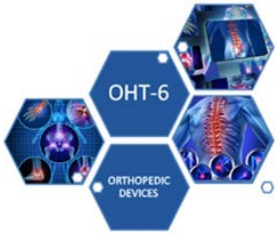


Medical Device Reports

FDA

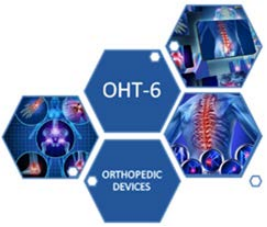
Limitations

- 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

- Search MAUDE database up to and including February 07, 2020
- Two different searches were performed to identify MDRs related to devices under the LZJ product code: one search was conducted using product code LZJ and one search was conducted using brand names that include ‘toe’.
- Our search resulted in 40 unique MDRs. The reports were received between April 1994 and September 2019. However, the method of fixation could not be confirmed.

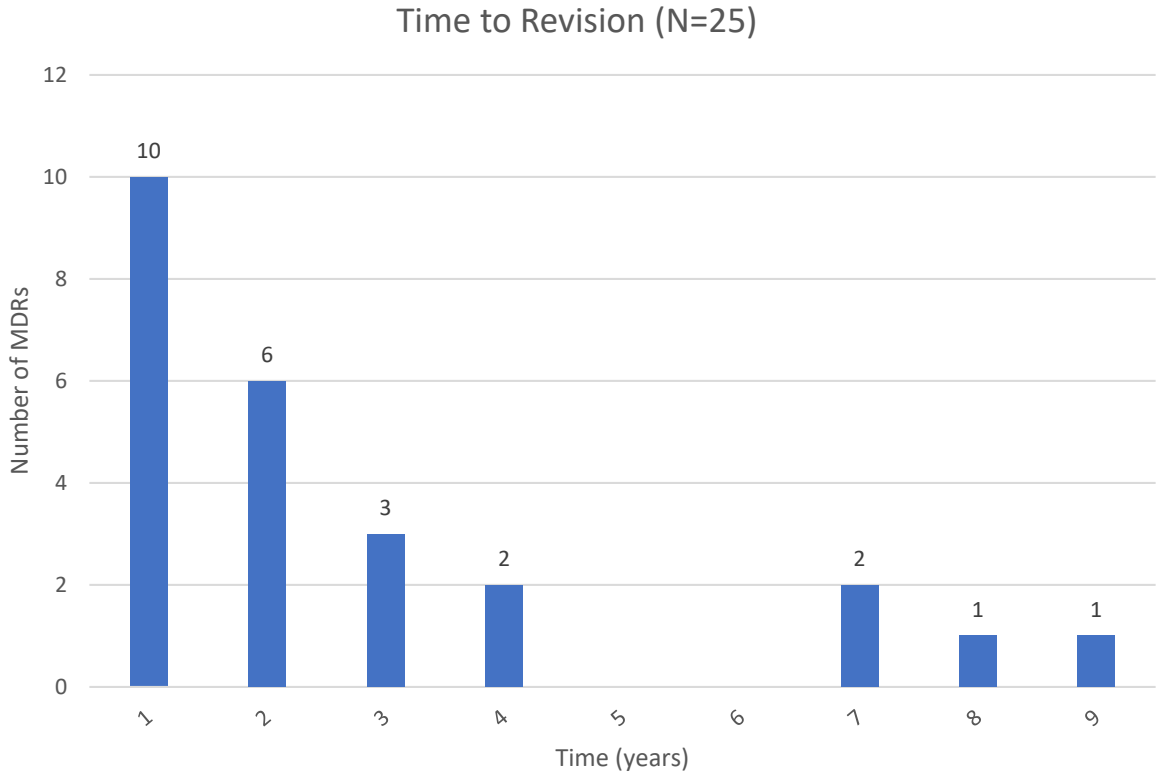


Medical Device Reports

MAUDE Results

Adverse Event	Count
Removal/Revision (includes 1 revision expected, 1 revision planned, 2 revisions recommended)	31
Pain	21
Loose (includes 2 lucencies)	12
Limited/Loss of range of motion (includes 1 no range of motion)	7
Swelling	5
Bone erosion/loss	4
Device Failure (2 poly separated from implant, 1 fracture of device, 1 cobalt chrome peeled off head of implant)	4
Reaction (1 multiple chemical sensitivity, 1 allergic reaction, 2 metallosis)	4
Migration	3
Discoloration	2

Medical Device Reports



Risks to Health

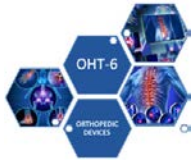
FDA has identified the following risks to health for cemented total first metatarsophalangeal (MTP) replacement devices based upon literature findings, the Manufacturer and User facility Device Experience (MAUDE) database, and the risks associated with total joint arthroplasty devices; however, this list may not be exhaustive:

Risks to Health

Identified Potential Risks	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.

Risks to Health

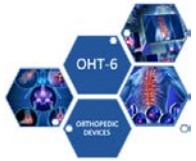
Identified Potential Risks	Description/Example
4. Sesamoid pathology	There is a risk of sesamoid pathology (e.g., subluxation, arthrosis of the metatarso-sesamoid junction) associated with total MTP joint replacement which may cause pain and loss of function.
5. Recurrence of the hallux deformity	There 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.



Risks to Health

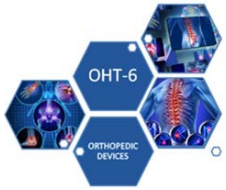
FDA

Identified Potential Risks	Description/Example
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.



Risks to Health

The Panel will be asked to comment on whether this is an accurate list of all of the risks in the overall risk assessment of cemented total first MTP joint implants under product code “LZJ.” In addition, the Panel will be asked to comment on whether any additional risks should be included in the overall risk assessment of these cemented total first MTP Joint Implants.



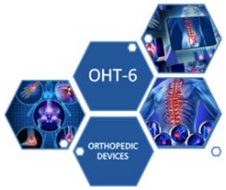
Risks & Mitigations

FDA

Risks to Health and Potential Mitigation Measures

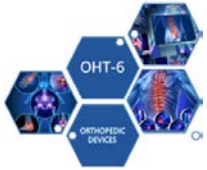
Identified Risk	Potential Mitigation Measure
Failure at the bone/implant interface (e.g., Lack of hallux purchase; Implant migration; Loosening of the prosthesis)	Design Characteristics Clinical Information* Labeling Non-clinical Performance Testing
Fracturing of the metatarsal head or base of the proximal 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

*** 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).**



Risks & Mitigations

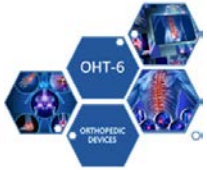
Identified Risk	Potential Mitigation Measure
Recurrence of the hallux deformity	Labeling
Painful/limited first MTPJ range of motion	Design Characteristics Labeling Non-clinical Performance Testing
Implant breakage or disassociation of components	Design Characteristics Non-clinical Performance Testing Labeling
Infection	Cleaning and Sterilization Validation
Dislocation/Subluxation	Design Characteristics Non-clinical Performance Testing
Use Error	Labeling Non-clinical Performance Testing



Risks & Mitigations

Identified Risk	Potential Mitigation Measure
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*

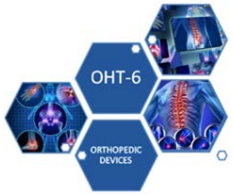
* Clinical information may come from a variety of sources, premarket or postmarket, including but not limited to, prospective or retrospective studies, literature, and real-world evidence sources (e.g., registries or electronic health records).



Risks & Mitigations

The Panel will be asked to discuss each of these potential controls and whether it, either alone or in combination with others, adequately mitigates the identified risk(s).

In addition, the risks associated with multiple secondary surgeries are particularly significant and possibly long-lasting. The Panel will be asked to 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. The Panel will be asked to comment on the recommended mitigations to address this risk.

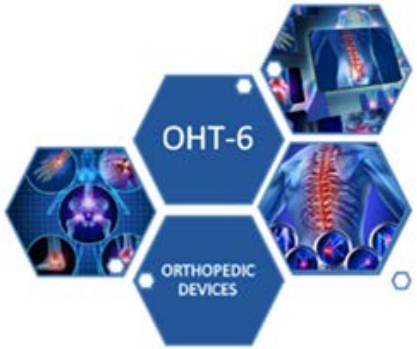


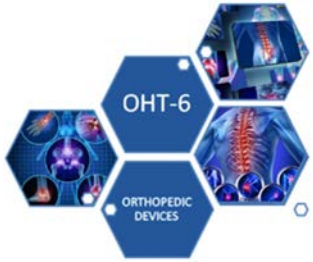
Proposed Classification

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.

Considering all information in the panel package, the panel will be asked to comment on the classification recommendation for cemented total first MTP joint implants.

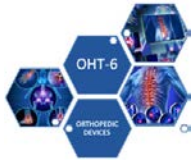
Thank You





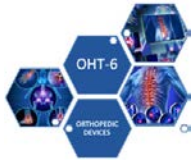
U.S. FOOD & DRUG ADMINISTRATION

Questions to Panel



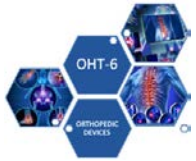
Question 1 to Panel

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.



Question 2 to Panel

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.

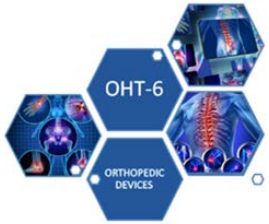


Question 2 to Panel (Cont'd)

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.



Question 3 to Panel

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 proposed classification, please provide your rationale for recommending a different classification.