April 5, 2024

Onkos Surgical
Gene Kulesha
Senior Director - Advanced Engineering
77 East Halsey Rd
Parsippany, New Jersey 07054

Re: DEN210058
Trade/Device Name: ELEOSx™ Limb Salvage System
Regulation Number: 21 CFR 888.3900
Regulation Name: Limb and joint salvage device with quaternary ammonium compound coating
Regulatory Class: Class II
Product Code: QZZ
Dated: December 30, 2021
Received: January 4, 2022

Dear Gene Kulesha:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the ELEOSx™ Limb Salvage System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The ELEOS™/ELEOSx™ Limb Salvage System is indicated for resection and replacement of the proximal femur, intercalary portion of the femur, total femur, distal femur, and proximal tibia in skeletally mature patients with the following conditions:
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> 1) Non-inflammatory degenerative joint disease such as osteoarthritis, traumatic arthritis, avascular necrosis, ankylosis, protrusion acetabuli, and painful hip dysplasia;
> 2) Inflammatory degenerative joint disease such as rheumatoid arthritis;
> 3) Correction of functional deformity;
> 4) Revision procedures where other treatments or devices have failed; and,
> 5) Treatment of fractures that are unmanageable using other techniques.
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> The ELEOS™/ELEOSx™ Limb Salvage System is also indicated for procedures where resection and replacement of the proximal femur, intercalary portion of the femur, total femur, distal femur, and proximal tibia is required with the following conditions:
>
> 1) Patients suffering from severe arthropathy of the hip and/or knee that does not respond to any conservative therapy or better alternative surgical treatment;

2) Surgical intervention for severe trauma, revision hip or knee arthroplasties, and/or Oncology indications.
3) Metastatic diseases

The ELEOSx™ MDPB coating, where applied, is intended to reduce bacterial contamination prior to implantation resulting from deposition in the operating room on the surface of the device components. The clinical impact associated with the MDPB coating, including prevention of infection or reduction of infection risk in patients, has not been evaluated in human clinical trials. The MDPB coating is not intended to treat existing infections and does not act within or on the body.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the ELEOSx™ Limb Salvage System, and substantially equivalent devices of this generic type, into Class II under the generic name limb and joint salvage device with quaternary ammonium compound coating.

FDA identifies this generic type of device as:

Limb and joint salvage device with quaternary ammonium compound coating. A limb and joint salvage device with quaternary ammonium compound coating is a metallic implant with or without polymer bearing for bone and joint replacement. Implants are for resection and replacement of an extremity bone (including the entire bone, epiphyseal bone, metaphyseal bone, or diaphyseal bone), or an extremity bone and the surrounding joint(s) in a skeletally mature patient. The device includes a quaternary ammonium compound coating that is covalently bonded to the device. Where applied, the coating is intended to reduce microbial contamination on the surface of the device prior to implantation. The device does not contain antimicrobial agents that act within or on the body and this device type does not include combination products.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On January 4, 2022, FDA received your De Novo requesting classification of the ELEOSx™ Limb Salvage System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the ELEOSx™ Limb Salvage System into class I or II, it is necessary that the proposed class have sufficient

regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the ELEOSx™ Limb Salvage System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	**Mitigation Measures**
Antimicrobial resistance	Antimicrobial resistance analysis
Loss of implant integrity and function leading to revision	Non-clinical performance testing Shelf life testing Labeling
Adverse tissue reaction	Animal performance testing Biocompatibility evaluation Non-clinical performance testing Pyrogenicity testing
Infection	Non-clinical performance testing Sterilization validation Shelf life testing Reprocessing validation Labeling

In combination with the general controls of the FD&C Act, the limb and joint salvage device with quaternary ammonium compound coating is subject to the following special controls:

(1) Animal performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Animal testing must include imaging, histology, and histomorphometry to assess bone formation, healing, and tissue response at relevant timepoints over the course of healing.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and include the following:
   (i) Evaluation of the static and dynamic performance of the implant;
   (ii) Evaluation of coated implant initial fixation;
   (iii) Evaluation of coating integrity;
   (iv) Evaluation of range of motion;
   (v) Evaluation of articulating bearing wear and bearing material;
   (vi) Evaluation of implant disassembly;
   (vii) Evaluation of fretting and corrosion;
   (viii) Evaluation of antimicrobial performance with clinically relevant microbial species; and
   (ix) Coating characterization, including a detailed description of the substrate morphology and coating process and an evaluation of coating physicochemical properties such as density, thickness, chemistry, and uniformity.

(3) An analysis must be provided that identifies and evaluates any contribution to the development and spread of antimicrobial resistance.

(4) An analysis or information must be provided to support that the antimicrobial does not act within or on the body.

(5) The patient-contacting components of the device must be demonstrated to be biocompatible.

(6) Performance data must support the sterility and pyrogenicity of the device components intended to be provided sterile.

(7) Performance data must validate the reprocessing instructions for the reusable instrumentation to be used with the device.

(8) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(9) Labeling must include the following:
   (i) Identification of device materials;
   (ii) A shelf life; and
   (iii) Instructions for removal/revision procedures.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the limb and joint salvage device with quaternary ammonium compound coating they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug

Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Alex Rodriguez at (301) 837-7247.

Sincerely,

Raquel A. Peat -S

CAPT Raquel Peat, PhD, MPH, USPHS
Director
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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