July 28, 2021

Onkos Surgical
Matthew (Matt) Vernak
Vice President, Quality and Regulatory
77 East Halsey Rd
Parsippany, New Jersey 07054

Re: K211677
Trade/Device Name: ELEOS™ Limb Salvage System
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee Joint Femorotibial Metal/Polymer Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: KRO, JDI, JWH, LPH, LZO
Dated: June 1, 2021
Received: June 1, 2021

Dear Matthew (Matt) Vernak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, 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).

Sincerely,

Ting Song, PhD
Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211677

Device Name
ELEOS™ Limb Salvage System

Indications for Use *(Describe)*
The ELEOS™ 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:

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.

The ELEOS 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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(k) Summary

5.1. Submitter

Onkos Surgical, Inc.
77 East Halsey Road
Parsippany, NJ 07054
Phone: (551) 579-1081
Contact Person: Matthew Vernak
Email: mvernak@onkossurgical.com

Date Prepared: 28-Jul-2021

5.2. Device

Name of Device:	ELEOS™ Limb Salvage System
Common Name:	Limb Salvage System
Classification Name:	21 CFR 888.3510, Prosthesis, Knee, Femorotibial, Constrained, Metal Polymer, Cemented 21 CFR 888.3350, Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented 21 CFR 888.3560, Knee joint patellofemorotibial polymer/metal/polymer semi- constrained cemented prosthesis 21 CFR 888.3358 Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous, Uncemented 21 CFR 888.3353, Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer Cemented or Non-Porous, Uncemented
Regulatory Class:	II
Product Code(s):	KRO JDI JWH LPH LZO

5.3. Predicate Device

ELEOS™ Limb Salvage System, Onkos Surgical, Inc., K161520 (Primary Predicate)
Orthogenesis LPS System, DePuy, Inc., K003182 (Predicate)

5.4. Device Description

The Onkos Surgical ELEOS™ Limb Salvage System consists of components that are used in the reconstruction of the lower limb. The reconstruction applications are proximal femur, intercalary portion of the femur, distal femur, total femur, proximal tibia, and hinged knee. The ELEOS Limb Salvage components are femoral head, proximal femur, female stem, mid-section, segmental stem, distal femur, tibial hinge assembly, axial pin, tibial poly spacer, tibial baseplate, male-male mid-

section, resurfacing femur, proximal tibia, patella, stem extension, and tibial wedges and augments. Instrumentation is provided non-sterile in surgical trays which are to be re-processed per validated instructions.

	RECONSTRUCTION APPLICATIONS					
Components	Proximal Femur	Intercalary	Distal Femur	Total Femur	Proximal Tibia	Hinged Knee
Femoral head	✓			✓		
Proximal Femur	✓			✓		
Female Stem		✓				
Mid-Section	✓	✓	✓	✓	✓	
Segmental Stem	✓	✓	✓		✓	
Distal Femur			✓	✓		
Tibial Hinge Component			✓	✓	✓	✓
Axial Pin			✓	✓	✓	✓
Tibial Poly Spacer			✓	✓	✓	✓
Tibial Baseplate			✓	✓		✓
Male-Male Midsection				✓		
Resurfacing Femur					✓	✓
Proximal Tibia					✓	
Patella[1]			✓	✓	✓	✓
Wedges and Augments[1]			✓	✓		✓
Stem Extensions[1]			✓	✓	✓	✓

1 – These implants are optional for each procedure. The surgeon shall use their medical judgement to determine if these implants are necessary based on factor such as patient bone quality, joint stability, and pathology.

The implants are single use devices.

5.5. Indications for Use

The ELEOS™ 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:

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.

The ELEOS 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

5.6. Comparison of Technological Characteristics with the Predicate Device

The subject device incorporates a new indication for use, intercalary replacement. This is in addition to the current indications of the primary predicate ELEOS Limb Salvage System and consistent with the indications of the predicate DePuy LPS System. The subject device is a line extension to the primary predicate device and can be used interchangeably with existing system components.

The design of the female stem will utilize the same material, segmental taper, cement flutes, and length as the primary predicate, ELEOS Limb Salvage System.

5.7. Performance Data

A risk-based evaluation of the subject and predicate device determined that the addition of the female stem to complete an intercalary replacement does not raise new concerns with respect to safety and/or effectiveness of the device. This is demonstrated by no new or increased risks related to loosening, subsidence, fatigue, dissociation, and/or fretting corrosion compared to the primary predicate device. Therefore, additional performance testing was not required to support this submission.

5.8 Clinical Data

Clinical data was not deemed necessary for the subject device.

5.9 Conclusions

Based on the test results and supporting documentation provided in this premarket notification, the subject ELEOS Limb Salvage System is substantially equivalent to the primary predicate, ELEOS Limb Salvage System, and predicate, Orthogenesis LPS System. The content in this premarket notification demonstrates that:

- any differences do not raise new questions of safety and effectiveness;
- and the proposed device is at least as safe and effective as the legally marketed predicate devices.