Onkos Surgical
Matthew Vernak
Vice President, Quality, Regulatory and Product Development
77 East Halsey Rd
Parsippany, New Jersey 07054

February 5, 2021

Re: K203588
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, JWH, JDI, LPH, LZO
Dated: December 8, 2020
Received: December 8, 2020

Dear Matthew 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,

Vesa Vuniqi
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)*
K203588

Device Name
ELEOS™ Limb Salvage System

Indications for Use *(Describe)*

ELEOS™ Limb Salvage System with Hip Components:
Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1) Non-inflammatory degenerative joint disease such as osteoarthritis, 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.

Limb salvage system is also indicated for procedures where radical resection and replacement of the proximal, distal and/or total femur is required with the following conditions:

1) Patients suffering from severe arthropathy of the hip that does not respond to any conservative therapy or better alternative surgical treatment;
2) Surgical intervention for severe trauma, revision hip arthroplasties, and/or Oncology indications.
3) Metastatic diseases

ELEOS™ Limb Salvage System with Knee Components:
Indicated for cemented use in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with the following conditions:

1) Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2) Inflammatory degenerative joint disease including 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.

Limb salvage system is also indicated for procedures where radical resection and replacement of the proximal tibia is required with the following conditions:
1) Patients suffering from severe arthropathy of the knee that does not respond to any conservative therapy or better alternative surgical treatment;
2) Surgical intervention for severe trauma, revision 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.

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"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: 04-Feb-2021

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 888.3560, Knee joint patellofemorotibial polymer/metal/polymer semi- constrained cemented prosthesis 21 CFR 888.3350, Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented 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 JWH JDI LPH LZO

5.3. Predicate Device

ELEOS™ Limb Salvage System, Onkos Surgical, Inc., K161520 (Predicate)
Orthopaedic Salvage System (OSS), Biomet, K052685 (Reference Device)

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, distal femur, total femur, proximal tibia, and hinged knee. The ELEOS Limb Salvage components are femoral head, proximal femur, mid-section, stem, distal femur, tibial hinge component, axial pin, tibial poly spacer, tibial baseplate, male-male mid-section, resurfacing femur, proximal tibia,

tapered screws, patella, stem extension, 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	Distal Femur	Total Femur	Proximal Tibia	Hinged Knee
Femoral head	✓		✓		
Proximal Femur	✓		✓		
Mid-Section	✓	✓	✓	✓	
Segmental Stem	✓	✓		✓	
Distal Femur		✓	✓		
Tibial Hinge Component		✓	✓	✓	✓
Axial Pin		✓	✓	✓	✓
Tibial Poly Spacer		✓	✓	✓	✓
Tibial Baseplate[1]		✓	✓		✓
Male-Male Mid-Section			✓		
Resurfacing Femur[1]				✓	✓
Proximal Tibia				✓	
Tapered Screws[1]		✓	✓	✓	✓
Patella[2]		✓	✓	✓	✓
Wedges and Augments[2]		✓	✓		✓
Stem Extensions[2]		✓	✓	✓	✓

1 – The Resurfacing Femur and Tibial Baseplate have the option for addition of a tapered screw between the respective component and a stem extension. The surgeon shall use their medical judgement to determine if the additional fixation is necessary based on factors such as patient bone quality, joint stability, and pathology.

2 – 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

ELEOS™ Limb Salvage System with Hip Components:

Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1) Non-inflammatory degenerative joint disease such as osteoarthritis, avascularnecrosis, 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.

Limb salvage system is also indicated for procedures where radical resection and replacement of the proximal, distal and/or total femur is required with the following conditions:

1) Patients suffering from severe arthropathy of the hip that does not respond to any conservative therapy or better alternative surgical treatment;
2) Surgical intervention for severe trauma, revision hip arthroplasties, and/or Oncology indications.
3) Metastatic diseases

ELEOS™ Limb Salvage System Knee Components:

Indicated for cemented use in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with the following conditions:

1) Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2) Inflammatory degenerative joint disease including 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.

Limb salvage system is also indicated for procedures where radical resection and replacement of the proximal tibia is required with the following conditions:

1) Patients suffering from severe arthropathy of the knee that does not respond to any conservative therapy or better alternative surgical treatment;
2) Surgical intervention for severe trauma, revision knee arthroplasties, and/or Oncology indications.
3) Metastatic diseases

5.6. Comparison of Technological Characteristics with the Predicate Device

The primary difference between the subject device and the predicate device is the option to use a tapered screw between the resurfacing femur and tibial baseplate components and corresponding stem extension. The tapered screw will be manufactured from Titanium-6Aluminum-4Vanadium (TAV) ELI per ASTM F136 and offered in two sizes (0.650” for use with the tibial baseplate and 1” for use with the resurfacing femur). To accommodate the screw, the resurfacing femur was modified to remove material between the condyles to allow insertion of a tapered screw between the resurfacing femur and stem extension after impaction of the tapered connections. This modification was incorporated as not to affect any of the bearing surfaces. Additionally, a tapered hole was incorporated into the sleeve of the tibial baseplate to allow insertion of a tapered screw between the tibial baseplate and stem extension after impaction of the tapered connections.

5.7. Performance Data

The following performance data are provided in support of substantial equivalence:

5.7.1 Mechanical Testing

Onkos Surgical has evaluated the subject devices to demonstrate substantial equivalence to the predicate devices. The following bench testing was completed and the results of support the subject devices are equivalent to the predicate device:

- Fatigue testing per ASTM F1800, Standard Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements and ASTM F2083, Standard Specification for Knee Replacement Prosthesis
- Evaluation of fretting corrosion for mating surfaces post fatigue testing
- Evaluation of screw loosening post fatigue testing

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 predicate, ELEOS Limb Salvage 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 device.