December 11, 2020

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

Re: K203090
Trade/Device Name: ELEOS™ Limb Salvage System featuring BIOGRIP™
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JDI, KRO, JWH, LPH, LZO
Dated: October 13, 2020
Received: October 13, 2020

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, Ph.D., R.A.C.
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)*
K203090

Device Name
ELEOS™ Limb Salvage System with BIOGRIP™

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.

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: 11-Oct-2020

5.2. Device

Name of Device:	ELEOS™ Limb Salvage System with BIOGRIP™
Common Name:	Limb Salvage System
Classification Name:	21 CFR 888.3350, Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented 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 888.3358 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):	JDI KRO JWH LPH LZO

5.3. Predicate Device

ELEOS™ Limb Salvage System, Onkos Surgical, Inc., K161520

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 hinge femur, tibial hinge assembly, axial pin, tibial poly spacer, tibial sleeve, male-male mid-section, resurfacing hinge femur, and proximal tibia, patella, stem extension, modular collar, tibial wedges and augments.

Instrumentation is provided non-sterile in surgical trays which are to be re-processed per the validated instructions stated below.

	RECONSTRUCTION APPLICATIONS				
Components	Proximal Femur	Distal Femur	Total Femur	Proximal Tibia	Hinged Knee
Femoral head	✓		✓		
Proximal Femur	✓		✓		
Mid-Section	✓	✓	✓	✓	
Segmental Stem	✓	✓		✓	
Modular Collar	✓	✓		✓	
Distal Femur		✓	✓		
Tibial Hinge Component		✓	✓	✓	✓
Axial Pin		✓	✓	✓	✓
Tibial Poly Spacer		✓	✓	✓	✓
Tibial Baseplate		✓	✓		✓
Male-Male Mid-Section			✓		
Resurfacing Hinge Femur				✓	✓
Proximal Tibia[1]				✓	
Patella[2]		✓	✓	✓	✓
Wedges and Augments[2]		✓	✓		✓
Stem Extensions[2]		✓	✓	✓	✓

1 – Bolded components are offered with BIOGRIP™ porous technology.

2 - These implants are optional for each procedure. The surgeon shall use his/her 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, 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

5.6. Comparison of Technological Characteristics with the Predicate Device

The primary difference between the subject implant, which is a line extension to the predicate device system, is the manufacturing process used. Specifically, an additive manufacturing processes is used to create the ELEOS BIOGRIP™ Proximal Tibia. The implant incorporates an additive porous surface (replacing titanium plasma) and additional suture holes are incorporated to better facilitate approximation of soft tissue and support bony apposition. Mechanical (both static and fatigue) and biocompatibility testing have demonstrated that the subjected device is substantially equivalent to the predicate system.

5.7. Performance Data

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

5.7.1 Biocompatibility

The biocompatibility evaluation for the ELEOS BIOGRIP™ Proximal Tibia was conducted in accordance with FDA's Guidance for Industry and FDA Staff, "Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a

Risk Management Process" issued June 16, 2016. The subject device is a permanent contact device manufactured from printed Ti6Al4V. The following biocompatibility tests were performed on each material group to ensure biocompatibility:

- Cytotoxicity (per ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity)
- Sensitization (per ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization)
- Irritation (per ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization)
- Systemic Toxicity: Acute (per ISO 10993-11, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity)
- Systemic Toxicity: Material Mediated Pyrogenicity (per ISO 10993-11, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity, and ST72:2011/(R)2016, Bacterial endotoxins - Test methods routine monitoring and alternatives to batch testing)
- Genotoxicity (per ISO 10993-3, Biological evaluation of medical devices - Part 3: Tests for genotoxicity carcinogenicity and reproductive toxicity)
- Chemical Characterization (per ISO 10993-18, Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process)
- Toxicological Risk Assessment (per ISO 10993-17, Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances)

The bacterial endotoxin test was performed to verify that the subject implants meet the 20 endotoxin units (EU)/device pyrogen limit specification. Testing was successfully performed, and it was confirmed that the subject devices meet the 20 EU/device testing limit for general medical devices that are implanted as outlined in ANSI/AAMI ST72: Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing and USP<161>, Medical Devices – Bacterial Endotoxin and Pyrogen Tests. Testing to monitor pyrogens will be performed periodically.

5.7.2. Mechanical Testing

Onkos Surgical has evaluated the subject devices to demonstrate substantial equivalence to the predicate devices. The following FDA Guidance documents were consulted to select the bench tests:

- *FDA Guidance:* "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement", Issued 28-Apr-1994

The following bench testing was completed and the results of support the subject devices are equivalent to the predicate device:

- ASTM F1044 - Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings

- ASTM F1147 - Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings
- ASTM F1160: Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings
- ASTM F1854 - Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants
- ASTM F1978 - Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser
- ASTM F2083, Standard Specification for Knee Replacement Prosthesis
- ISO13179-1:2014: Implants for surgery — Plasma sprayed unalloyed titanium coatings on metallic surgical implants

5.8 Clinical Data

Clinical data was not deemed necessary for the subject device.

5.9 Design Validation

Design Validation was performed for the subject implant using a cadaver lab. Design Validation demonstrated the subject implant and existing instruments function as intended and user needs were met.

5.10 Conclusions

Based on the test results and supporting documentation provided in this premarket notification, the subject ELEOS Limb Salvage System with BIOGRIP™ is substantially equivalent to the predicate device, 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.