DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 28, 2016

Onkos Surgical, Inc.
Jan Triani
Sr. Director Quality Assurance and Regulatory Affairs
77 East Halsey Road
Parsippany, New Jersey 07054

Re: K161520
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: September 28, 2016
Received: September 30, 2016

Dear Jan Triani:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161520

Device Name
ELEOS LIMB SALVAGE SYSTEM

Indications for Use *(Describe)*

ELEOS™ Limb Salvage System 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 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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5. 510(k) Summary

I. SUBMITTER

Onkos Surgical, Inc.
77 East Halsey Road
Parsippany, NJ 07054

Phone: (201)543-9388

Contact Person: Jan Triani
Email: jtriani@onkossurgical.com

Date Prepared: October 27, 2016

II. DEVICE

Name of Device:	ELEOS™ Limb Salvage System
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:	JDI/KRO JWH LPH LZO

III. PREDICATE DEVICE

GUARDIAN® Limb Salvage System, K013035
ADVANCE® Modular Tibial Component, K973524
LINEAGE® Acetabular System, K002149
SLT Femoral Heads, K932222

No reference devices were used in this submission.

IV. 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, 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, 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	✓		✓		
Mid-Section	✓	✓	✓	✓	
Segmental Stem	✓	✓		✓	
Distal Femur		✓	✓		
Tibial Hinge Component		✓	✓	✓	✓
Axial Pin		✓	✓	✓	✓
Tibial Poly Spacer		✓	✓	✓	✓
Tibial Baseplate		✓	✓		✓
Male-Male Mid-Section			✓		
Resurfacing Hinge Femur				✓	✓
Proximal Tibia				✓	
Patella		✓*	✓*	✓*	✓*
Wedges and Augments		✓*	✓*	✓*	✓*
Stem Extension		✓*	✓*	✓*	✓*

**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.*

V. INDICATIONS FOR USE

ELEOS™ Limb Salvage System 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 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

VI. COMPARISON OF TECHNOLOGICAL CHARACTERSTICS WITH THE PREDICATE DEVICE

The predicate devices and the subject device are the same. The same materials, technology and sterilization methods are used to manufacture the subject device. The predicate device manufacturer is the contract manufacturer of the subject device. There are no technological differences between the two systems.

VII. PERFORMANCE DATA

No performance data is provided. A copy of the full 510(k) for the predicate device (K013035) is provided because there are no technological differences between the subject and predicate devices. Pyrogenicity was assessed using the LAL test which identified an acceptable endotoxin limit. Testing to monitor pyrogens will be performed using periodic testing.

VIII. CONCLUSIONS

Since the subject device is identical with respect to fit, form, function and manufacturing processes as the predicate device, the ELEOS™ Limb Salvage System has the same safety and effectiveness profile as the predicate device.