October 29, 2026

Onkos Surgical, Inc.
Arley Perez
Vice President, Product Development
77 E. Halsey Rd.
Parsippany, New Jersey 07054

Re: K263628
Trade/Device Name: ELEOS™ Limb Salvage System with NanoCept® Technology (Proximal Tibia) (AM-25002200-C)
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, KRO
Dated: September 30, 2026
Received: September 30, 2026

Dear Arley Perez:

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 (the 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 available 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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. Additional information about changes that

may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

LIMIN SUN -S

Limin Sun, Ph.D.
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)*
K263628

Device Name
ELEOS™ Limb Salvage System with NanoCept® Technology (Proximal Tibia) (AM-25002200-C)

Indications for Use *(Describe)*
The ELEOS™ and ELEOS™ Limb Salvage System with NanoCept® Technology 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™ and ELEOS™ Limb Salvage System with NanoCept® Technology 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 ELEOS™ Limb Salvage System with NanoCept® Technology 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.

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:

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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."*

# 510(k) Summary

| | |
|---|---|
| **Date Prepared:** | October 29, 2026 |
| **Applicant:** | Onkos Surgical, Inc<br>77 East Halsey Road<br>Parsippany, NJ 07054 |
| **Establishment Registration Number:** | 2184009 |
| **Contact Person:** | Arley Perez<br>Vice President, Product Development<br>Phone: 239-216-0701<br>Email: aperez@onkossurgical.com<br><br>Gene Kulesha<br>Executive Director, Advanced Technologies<br>Phone: 973-809-6088<br>Email: gkulesha@onkossurgical.com |
| **Trade Name:** | ELEOS™ Limb Salvage System with NanoCept® Technology (Proximal Tibia) (AM-25002200-C) |
| **Common Name:** | Limb and joint salvage device with quaternary ammonium compound coating |
| **Classification Name:** | Limb And Joint Salvage Device with Coating for Bacteria Reduction |
| **Classification:** | Class II (with special controls) |
| **Regulation Number:** | 21 CFR 888.3900 |
| **Product Code:** | QZZ |
| **Subsequent Product Code:** | KRO |
| **Predicate Device:** | ELEOS™ Limb Salvage System with NanoCept® Technology (Proximal Tibia) (AM-25002200-C) (K252920) |
| **Reference Device:** | ELEOS™ Proximal Tibia with BIOGRIP™ Porous Technology (K203090) |

## Device Description

The ELEOS™ Limb Salvage System with NanoCept® Technology is a reconstruction implant system for patients who require limb salvage to treat significant bone loss due to cancer, trauma, or previous surgical procedures. Certain components of the system include an antibacterial coating, 12-methacryloyloxydodecyl pyridinium bromide (MDPB), which is covalently bound to the implant surface and is intended to reduce bacterial contamination on the device surface prior to implantation.

The subject device is the MDPB-coated cobalt-chromium (CoCr) proximal tibia component (AM-25002200-C) of the proximal tibia assembly, cleared under K252920. The purpose of this Special 510(k) is to add two anterior-posterior suture holes to the component to provide additional options for securing sutures. The substrate material, MDPB coating, taper interface, sterilization, packaging, and shelf life are unchanged.

## Indications for Use

The ELEOS™ and ELEOS™ Limb Salvage System with NanoCept® Technology 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;
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## Technological Comparison to Predicate

The subject device has the same intended use (limb salvage and joint reconstruction), operating principle, substrate material (CoCrMo), MDPB coating, single female taper interface, resection length, sterilization method, and packaging as the predicate device (K252920). The subject device differs from the predicate only by the addition of two anterior-posterior suture holes with controlled edge radii. These differences do not raise different questions of safety and effectiveness.

## Performance Data

No new performance testing was conducted. The following supporting information demonstrates the performance of the subject device:

- Engineering rationale that the AP suture holes do not create a new worst case for structural performance;
- Fretting and corrosion engineering analysis;
- Coating-process rationale and existing per-lot coating-density release testing;
- Cumulative MDPB-coated surface-area analysis; and
- Sterilization, packaging, shelf life, pouch and carton labels, and Instructions for Use remain unchanged.

## Conclusion

The information included in this submission demonstrates that the ELEOS™ Limb Salvage System with NanoCept® Technology (Proximal Tibia) (AM-25002200-C) is substantially equivalent to the predicate device, K252920.