October 15, 2025

Onkos Surgical, Inc.
Elizabeth Rose
Regulatory Affairs Contractor
77 East Halsey Road
Parsippany, New Jersey 07054

Re: K252920
Trade/Device Name: ELEOS™ Limb Salvage System with NanoCept® Technology
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 12, 2025
Received: September 12, 2025

Dear Elizabeth Rose:

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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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 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,

RYAN TROMBETTA -S

For: 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252920

Device Name
ELEOS™ Limb Salvage System with NanoCept® Technology

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.

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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 15, 2025**
Applicant:	Onkos Surgical, Inc 77 East Halsey Road Parsippany, NJ 07054
Establish Registration Number:	2184009
Contact Person:	Arley Perez Senior Director, Product Development Phone: 239-216-0701 Email: APerez@onkossurgical.com Elizabeth Rose Regulatory Affairs Phone: 423-252-9924 Email: erose@onkossurgical.com
Trade Name:	ELEOS™ Limb Salvage System with NanoCept® Technology
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, KRO
Primary Predicate:	ELEOSx™ Limb Salvage System
Submission Number:	DEN210058
Additional Predicate:	ELEOS™ Limb Salvage System
Submission Number:	K161520

Device Description

The Onkos Surgical ELEOS™ Limb Salvage System, a reconstruction implant system intended for joint replacement, limb salvage, and restoration of limb function. The subject technology consists of 510(k)-cleared limb salvage systems (i.e., ELEOS™ Limb Salvage System) and applies an antibacterial coating to certain cobalt chromium (CoCr) components.

The ELEOS™ Limb Salvage System with NanoCept® Technology includes components that have been modified with an antibacterial coating, which includes a covalently bound Quaternary Ammonium Compound (QAC), specifically 12-Methacryloyloxydodecyl Pyridinium Bromide (MDPB). The purpose of the antibacterial coating is to reduce bacterial contamination on the surface of the device prior to implantation, by killing bacteria external to the patient which deposit onto the device surface from the operating environment. This coating is not intended to act in or on the body of the patient but rather reduces contamination on the surface of the device prior to implantation.

The purpose of this 510(k) submission is to introduce the ELEOS™ Limb Salvage System with NanoCept® Technology (Proximal Tibia component of the Proximal Tibia assembly) manufactured with cobalt-chromium (CoCr) substrate material cleared in the original predicate device K161520 with an added MDPB coating used in the predicate ELEOSx™ Limb Salvage System DEN210058. This modification aims to expand the product portfolio by adding a CoCr proximal tibia with MDPB coating.

Indications for Use

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1) Non-inflammatory degenerative joint disease such as osteoarthritis, traumatic arthritis, avascular necrosis, ankylosis, protrusion acetabuli, and painful hip dysplasia;
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Technological Comparison to Predicate

The subject device is substantially equivalent to the predicate device as the subject device shares the same intended use—limb salvage and joint reconstruction—and operating principle, design,

materials, geometry, manufacturing, sterilization and packaging. The modification to apply the MDPB coating to the proximal tibia component of the proximal tibia assembly does not introduce new risks related to mechanical performance, coating characterization, or antibacterial efficacy.

Performance Data

No performance testing was conducted; however, this submission includes supporting information that demonstrates the subject device's performance:

- Fretting and Corrosion engineering analysis
- Coating integrity (handling) rationale
- Biocompatibility risk assessment

Conclusion

The information included in this submission demonstrates that the ELEOS Limb Salvage System with NanoCept® Technology is substantially equivalent to the legally marketed predicate devices, ELEOSx™ Limb Salvage System (DEN210058) and ELEOS™ Limb Salvage System (K161520).