January 30, 2023

Onkos Surgical, Inc.
Matthew Vernak
Vice President, Quality and Regulatory
77 East Halsey Road
Parsippany, New Jersey 07054

Re: K223348
Trade/Device Name: My3D® Personalized Pelvic Reconstruction
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH
Dated: December 20, 2022
Received: December 20, 2022

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,

Limin Sun -S

Limin Sun, PhD
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)*

K223348

Device Name

My3D® Personalized Pelvic Reconstruction

Indications for Use *(Describe)*

The My3D® Personalized Pelvic Reconstruction system is indicated for use in patients requiring reconstruction of the pelvis and/or hip joint due to disease, deformity, trauma, or revision procedures where other treatments or revisions have failed. The device is a combination of single use guided osteotomy instruments, a pelvic implant, screws, and acetabular/ femoral components. The pelvic implant is intended for cementless application in individuals where bone quality or bony defect size cannot support a standard sized acetabular implant. The pelvic implant is intended to be fixed to the remaining pelvic anatomy using compatible bone screws to create a prosthetic acetabulum. The reconstructed prosthetic acetabulum is intended to be used with a compatible cemented acetabular cup, dual mobility head (POLARCUP Insert), and femoral components to restore hip function.

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."

11. 510(k) Summary

Device Trade Name: My3D® Personalized Pelvic Reconstruction

Common Name: Hip Prosthesis

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

Contact:
Matthew Vernak
VP, Quality and Regulatory
Onkos Surgical, Inc.
77 East Halsey Road
Parsippany, NJ, 07054, USA
Phone: (551) 579-1081
Email: mvernak@onkossurgical.com

Prepared by:
Veronica Fleck
Director, Regulatory Affairs
MCRA, LLC
803 7th Street NW, Floor 3
Washington, DC 20001
Email: vfleck@mcra.com
Phone: 202.552.5837

Date Prepared: November 1, 2022

Classifications: 21 CFR §888.3358

Classification Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.

Class: II

Product Codes: LPH

Indications for Use:

The My3D® Personalized Pelvic Reconstruction system is indicated for use in patients requiring reconstruction of the pelvis and/or hip joint due to disease, deformity, trauma, or revision procedures where other treatments or revisions have failed. The device is a combination of single use guided osteotomy instruments, a pelvic implant, screws, and acetabular/ femoral components. The pelvic implant is intended for cementless application in individuals where bone quality or bony defect size cannot support a standard sized acetabular implant. The pelvic implant is intended to be fixed to the remaining pelvic

anatomy using compatible bone screws to create a prosthetic acetabulum. The reconstructed prosthetic acetabulum is intended to be used with a compatible cemented acetabular cup, dual mobility head (POLARCUP Insert), and femoral components to restore hip function.

Device Description:
The subject submission adds locking screw component options and associated instrumentation to the subject My3D® Personalized Pelvic Reconstruction system.

The My3D® Personalized Pelvic Reconstruction system is a patient specific combination of single use resection instruments, a pelvic implant, screws, acetabular, and femoral components. The system was developed to address conditions which require reconstruction of the acetabulum and hip joint.

This patient matched device is designed from inputs including imaging, diagnosis, and surgical approach. Together with the surgeon, these inputs are then translated via a design process to create patient specific implants and, if appropriate, instruments to reconstruct the patient's pelvis. If utilized, the patient specific instruments are used to resect the bone and allow for implantation of the patient matched pelvis. The joint is then reconstructed with a cemented acetabular cup, dual mobility head (POLARCUP Insert), and femoral components.

The implants and resection instruments are single use devices. Reusable instrumentation is provided non-sterile in surgical trays which are to be re-processed per validated instructions.

Primary Predicate Device:
The My3D® Personalized Pelvic Reconstruction system is substantially equivalent to the primary predicate device listed in **Table 11-1**, with regards to indications, basic design, materials, manufacturing, sizing, and performance.

Table 11-1: Primary Predicate Device

Device Name	Manufacturer	K-Number
My3D® Personalized Pelvic Reconstruction	Onkos Surgical, Inc.	K212815

Reference Devices:
The subject locking screw components of the My3D® Personalized Pelvic Reconstruction system are substantially equivalent to the reference devices listed in **Table 11-2**, with respect to design, materials, sizing, and mechanical performance. The NET Brand Small Fragment and Large Fragment Osteosynthesis Plating System (K150561) is referenced in support of the mechanical performance testing methodology for the subject device.

Table 11-2: Reference Devices

Device Name	Manufacturer	K-Number
NET Brand Small Fragment and Large Fragment Osteosynthesis Plating System (locking screw components)	Narang Medical Limited	K150561

Performance Testing Summary:
The subject device underwent torsional properties testing per ASTM F543-17, axial pullout testing per ASTM F543-17, and driving and removal torque testing per ASTM F543-17. Additionally, a stress analysis was performed to support the development of an engineering rationale demonstrating that the subject locking screws do not create a new worst-case for failure of the pelvic implant due to stress.

Comparison of Technological Characteristics:
The subject device was demonstrated to be substantially equivalent to the My3D® Personalized Pelvic Reconstruction primary predicate devices (K212815) with respect to indications, design, materials, manufacturing, sizing, principles of operation, and performance.

Conclusion:
The subject My3D® Personalized Pelvic Reconstruction system and primary predicate device cited above have the same intended use, indications for use, technological characteristics, are made of identical materials, and include similar implant designs. The subject and primary predicate devices are packaged in identical materials, are both provided non-sterile, and are intended to be sterilized by the end user via steam sterilization (autoclave). Based on the test results and supporting documentation provided in this 510(k) premarket notification, the subject My3D Personalized Pelvic Reconstruction has been demonstrated to be as safe, as effective, and is substantially equivalent to the legally marketed primary predicate, My3D® Personalized Pelvic Reconstruction (K212815).