July 6, 2022

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

Re: K212815
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: June 3, 2022
Received: June 6, 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,

for

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)*
K212815

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.

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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: 21-Jun-2022

5.2. Device

Name of Device:	My3D® Personalized Pelvic Reconstruction
Common Name:	Custom Flanged Acetabular Component
Classification Name:	21 CFR 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class:	II
Product Code(s):	LPH

5.3. Predicate Devices

Biomet's Patient Matched Pelvic Implant, K983035 (Primary Predicate)

3D System's VSP® Orthopedics System, K190044 and K211244 (Reference Device)

MicroPort's Second Generation Knee System, K894334 (Reference Device)

MicroPort's Lineage Acetabular System, K002149 (Reference Device)

Smith and Nephew's POLARCUP Dual Mobility System, K110135 (Reference Device)

Smith and Nephew's POLARSTEM Femoral Stems, K130728, K143739 (Reference Device)

Smith and Nephew's REDAPT Revision Femoral System, K151902 (Reference Device)

Smith and Nephew's REDAPT Sleeved Monolithic Revision Hip Stems, K162303 (Reference Device)

Smith and Nephew's FEMORAL HEADS, K021673, K963509

5.4. Device Description

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.

5.5. 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.

5.6. Comparison of Technological Characteristics with the Predicate Device

Both the predicate and subject device are both single use patient matched acetabular implants used to reconstruct the hip joint. The primary difference between the subject and predicate devices is that the subject device is additively manufactured and, when appropriate, utilizes patient specific resection instruments to prepare the pelvis for implantation.

5.7. Performance Data

The following testing was performed to support substantial equivalence of the devices:

- Evaluation of biocompatibility for implants and instruments per ISO 10993-1
- Manufacturing Residuals (Powder) Analysis
- Sterilization Validation
- Characterization and Mechanical Testing of the Porous Structure
- Flanged acetabular component fatigue testing
- Acetabular void fatigue testing
- Acetabular deformation testing

- Evaluation of Screw Performance
- Cadaveric Evaluation of the Design Process

5.8 Clinical Data

Clinical data were not deemed necessary for the subject device.

5.9 Conclusions

Based on the test results and supporting documentation provided in this premarket notification, the subject My3D Personalized Pelvic Reconstruction device is substantially equivalent to the predicate, Patient Matched Flanged Acetabular Component. 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.