August 20, 2021

Gillen Gonzales
Regulatory Affairs Specialist I
5677 Airline Road
Arlington, Tennessee 38002

Re: K202705
Trade/Device Name: Prime and DYNASTY® Additive Manufacturing Shells
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: OQG, OQI, LPH, LZO
Dated: July 19, 2021
Received: July 20, 2021

Dear Gillen Gonzales:

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, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202705

Device Name
Prime and DYNASTY® Additive Manufacturing Shells

Indications for Use *(Describe)*

The Prime and DYNASTY® Additive Manufacturing Shells are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

Indications for Use
1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2) inflammatory degenerative joint disease such as rheumatoid arthritis;
3) correction of functional deformity; and,
4) revision procedures where other treatments or devices have failed.

Shells with BIOFOAM® metal foam coating are intended only for uncemented arthroplasty.

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."

510(k) Summary

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the Prime and DYNASTY® Additive Manufacturing Shells.

Submitted by:	MicroPort Orthopedics Inc. 5677 Airline Road, Arlington, TN 38002 Phone: 866-872-0211 Fax: 855-446-2247
Date:	September 15, 2020
Contact Person:	Gillen Gonzales *Regulatory Affairs Specialist I*
Proprietary Name:	Prime and DYNASTY® Additive Manufacturing Shells
Common Name:	Uncemented Acetabular Shell
Classification Name and Reference:	21 CFR 888.3358- Hip joint/metal/polymer/metal semi-constrained porous-coated uncemented prosthesis- Class II 21 CFR 888.3353- Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis - Class II
Subject Product Code and Panel Code:	Orthopedics/87/OQG, OQI, LPH, LZO
Primary Predicate:	Prime BIOFOAM® Acetabular Shells (K170444)
Additional Predicates:	DYNASTY® Acetabular System (K082924) DYNASTY® BIOFOAM® Shell (K122382)
Reference Devices:	BIOFOAM® Additive Manufacturing (K170288)

DEVICE INFORMATION

A. Device Description

MicroPort Orthopedics Inc. is introducing the Prime and DYNASTY® Additive Manufacturing (AM) Shells as a line extension of its existing Prime and DYNASTY® Acetabular Systems. The Prime and DYNASTY® AM Shells are made from titanium alloy (Ti-6Al-4V) powder through an additive manufacturing process and are designed for cementless use on the bone interfacing surface. The device design is identical to its corresponding predicate devices. The design features of the Prime and DYNASTY® AM Shells are summarized below.

- Prime AM Shells:
  - Material of Shell and Porous Coating: Titanium Alloy (Ti-6Al-4V) AM powder
  - Available in the following configurations and their respective sizes:
    - Solid (46mm-68mm outer diameter)
    - Quad (42mm- 68mm outer diameter)
  - Sterilization: Gamma Sterilization

- DYNASTY® AM Shells:
  - Material of Shell and Porous Coating: Titanium Alloy (Ti-6Al-4V) AM powder
  - Available in the following configurations and their respective sizes:
    - Standard (46mm- 76mm outer diameter)
    - Primary (46mm-68mm outer diameter)
    - Revision (46mm-76mm outer diameter)
  - Sterilization: Gamma Sterilization

The subject implants are single-use only, are provided sterile, and are prescription only devices, intended to be implanted only by orthopedic specialists in an operating room setting.

B. Intended Use

The Prime and DYNASTY® Additive Manufacturing Shells are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

Indications for Use

1. Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio 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.

Shells with BIOFOAM® metal foam coating are intended only for uncemented arthroplasty.

C. Substantial Equivalence Information

The design features and materials of the subject devices are substantially equivalent to those of the predicate/reference devices. The indications for use are identical to the predicate devices. The fundamental scientific technology of the modified devices has not changed relative to the predicate devices. The safety and effectiveness of the subject devices are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

D. Nonclinical Testing

Non-clinical bench performance testing was conducted to evaluate and demonstrate the substantial equivalence of the subject Prime and DYNASTY® AM Shells to their legally marketed predicate and reference devices.

The testing and engineering analyses performed for the subject Prime and DYNASTY® AM Shells:

- The additively manufactured base material was evaluated for tensile strength, fatigue properties, elemental analysis, and morphological analysis.
- The subject BIOFOAM® coating was evaluated for tensile strength, elemental analysis, morphological analysis, shear strength, abrasion resistance, friction, and fatigue properties.
- The additively manufactured final finished device was evaluated for deformation and frictional torque, electrochemical corrosion, and shell fatigue.

Predicate nonclinical test results were leveraged to support the subject devices via equivalency rationale.

- MR Conditionality Assessments (Field Interactions, Artifacts, RF Heating)
- Push-out, Lever-out, Torque-out

A review of the testing data concludes that the subject devices are substantially equivalent to its identified legally marketed predicate and reference devices. Having met all acceptance criteria for mechanical testing performed on worst-case constructs, the subject Prime and DYNASTY® AM Shells do not introduce new or modified risks for safety and effectiveness.

E. Clinical Testing

Clinical data was not provided for the subject devices.

F. Sterilization Residuals

The subject Prime and DYNASTY® AM Shells were adopted into the current metal product gamma radiation sterilization family. The bacterial endotoxin test, also known as the Limulus amebocyte lysate (LAL) test, was performed using worst-case implants to verify that the subject implants meet the 20 endotoxin units (EU)/device pyrogen limit specification.

The existing testing was successfully performed and confirms that the worst-case implants for the metal product family meet the 20 EU/device limit for general implanted medical devices as outlined in ANSI/AAMI ST72 and USP <161>.

G. Component and Accessory Compatibility

The Prime AM shells are compatible with all 510(k)-cleared Prime A-Class® and E-Class® liners while the DYNASTY® AM shells are compatible with all 510(k)-cleared DYNASTY® A-Class® liners. Both Prime and DYNASTY® AM shells are compatible with MicroPort Orthopedics' 510(k)-cleared cancellous bone screws. The Prime and DYNASTY® AM shells are used as a system with MicroPort Orthopedics' 510(k)-cleared heads, stems, and femoral necks.

H. Biocompatibility

Biocompatibility was evaluated per ISO 10993-1 and FDA Guidance Document "*Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process'*", published June 16, 2016. Raw material and processing/packaging materials were considered in this risk-based assessment. The subject devices were determined to be biocompatible and to not present undue risk to the patient.

The chemical composition of the raw material (Ti-6Al-4V) and the intended patient contact of the subject implants are identical to the predicate devices.

I. Conclusions

The indications for use and fundamental scientific technology of the subject devices are identical to the predicate devices. Design features, materials information, predicate testing and analysis data provided in this premarket notification adequately support the substantial equivalence of Prime and DYNASTY® AM Shells.