August 24, 2021

MicroPort Orthopedics Inc.
Ryan Ross
Manager - Regulatory Affairs
5677 Airline Road
Arlington, Tennessee 38002

Re: K201157
Trade/Device Name: Prime BIOFOAM® Multi-Hole 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: MBL, LPH, LZO
Dated: August 11, 2021
Received: August 12, 2021

Dear Ryan Ross:

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)*

K201157

Device Name
Prime BIOFOAM® Multi-Hole Shells

Indications for Use *(Describe)*

The Prime Acetabular Cup System is 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® 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.

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510(k) Summary
Prime BIOFOAM® Multi-Hole Shell

In accordance with 21 CFR 807.92 and the Safe Medical Devices Act of 1990, this information serves as a Summary of Substantial Equivalence for the use of the Prime BIOFOAM® Multi-Hole Shell. The submission was prepared in accordance with FDA Guidance Document "Format for Traditional and Abbreviated 510(k)s", issued September 13, 2019.

Submitted by:	MicroPort Orthopedics Inc. 5677 Airline Road Arlington, TN 38002 USA
Date:	August 24, 2021
Contact Person:	Ryan Ross Sr. Manager, Regulatory Affairs Phone: (901) 867-4401 Fax: (901) 451-6018 Email: ryan.ross@ortho.microport.com
Proprietary Name:	Prime BIOFOAM® Multi-Hole Shell
Common Name:	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 Panel and Product Code(s):	Orthopedics/87/MBL, LPH, LZO

Legally Marketed Devices to which Substantial Equivalence is claimed:

Primary Predicate:	K170444	Prime Acetabular Cup System	MicroPort Orthopedics Inc.
Predicate Devices:	K122382	DYNASTY® BIOFOAM® Shell	MicroPort Orthopedics Inc.
	K082924	DYNASTY® BIOFOAM® Shell	MicroPort Orthopedics Inc.

DEVICE INFORMATION

A. Device Description

MicroPort is introducing the Prime BIOFOAM® Multi-Hole Shells as a line extension of its existing Prime Acetabular System (K170444, K171181, K180798, and K181598). The subject implants are single use only, are provided sterile, and are to be implanted only by orthopedic specialists in an operating room setting. Associated instrumentation is reusable, provided non-sterile, and are to be used only by orthopedic specialists in an operating room setting.

The Prime BIOFOAM® Multi-Hole Shell includes 10, 12, or 14 screw hole variations. The subject acetabular shells can be used with existing MicroPort devices listed in Section G, Table 3 to form a complete total hip system.

- Multi-Hole Acetabular Shells
  - Material: Ti alloy conforming to ASTM F620
  - Coating: Commercially Pure Ti Foam conforming to ASTM F67 (BIOFOAM®)
  - Outer diameters: 42mm to 68mm with 2 mm increments
  - Variants: 10, 12, or 14 screw holes
  - Sterilized using Gamma Radiation

B. Intended Use

The Prime Acetabular Cup System is 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® coating are intended only for uncemented arthroplasty.

C. Summary of Technological Characteristics

The design features and materials of the Prime BIOFOAM® Multi-Hole Shell are substantially equivalent to those of the predicate devices. The indications are identical to the predicate devices. The fundamental scientific technology of the subject devices has not change relative to the predicate devices. Sterilization methods are identical to the predicate devices.

Different from the predicate acetabular shells, which have 3 screw holes, the subject acetabular shell has 10, 12, or 14 screw holes dependent on shell size.

The safety and effectiveness of the subject devices are adequately supported by the substantial equivalence information, materials information, and analysis of data provided within this Premarket Notification.

D. Nonclinical Testing

Nonclinical bench testing was performed to evaluate and demonstrate the substantial equivalence of the subject Prime BIOFOAM® Multi-Hole Shells to their legally marketed predicate devices.

- Frictional Torque/Pinch Load, per ISO 7206-2 and ISO 7206-12
- Finite Element Analysis, per ASTM F3090
- Long-Term Shell Fatigue, per ASTM F1820, ASTM F2068, and ASTM F3090

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

- MR Conditionality Assessments (Field Interactions, Artifacts, RF Heating), per ASTM F2052, ASTM F2119, ASTM F2503, ASTM F2182

E. Clinical Testing

Clinical testing was not provided for the subject devices.

F. Biocompatibility

The intended patient contact and materials used in the subject implant devices are identical to the predicate devices.

All subject instruments have identical patient contact and materials as instrumentation cleared as part of K170444.

G. Instrumentation

The Prime BIOFOAM® Multi-Hole Shell uses existing instrumentation submitted as part of K170444. No new instrumentation is being introduced for the subject device.

H. Conclusion

Based on the intended use, indications for use, design features, the use of established well-known materials, and results of the nonclinical bench testing, the subject Prime BIOFOAM® Multi-Hole Shell is substantially equivalent to the legally marketed devices listed in this summary.