**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 15, 2017

Microport Orthopedics, Inc.
Ms. Grace Johnson-Bann
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

Re: K170288
Trade/Device Name: BIOFOAM® Additive Manufacturing (BIOFOAM® AM),
EVOLUTION® BIOFOAM® Tibial Base,
ADVANCE® BIOFOAM® Tibial Base,
DYNASTY® BIOFOAM® Acetabular Shell
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH, LZO
Dated: May 4, 2017
Received: May 5, 2017

Dear Ms. Johnson-Bann:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Vincent J. Devlin -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

K170288

Device Name

BIOFOAM® Additive Manufacturing (BIOFOAM® AM), ADVANCE® BIOFOAM® Tibial Base, EVOLUTION® BIOFOAM® Tibial Base, DYNASTY® BIOFOAM® Acetabular Shell

Indications for Use *(Describe)*

The ADVANCE® BIOFOAM® and EVOLUTION® BIOFOAM® tibial bases are indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

1. Non-inflammatory degenerative joint disease: including osteoarthritis, traumatic arthritis, or avascular necrosis;
2. Inflammatory degenerative joint disease, including rheumatoid arthritis;
3. Correction of functional deformity;
4. Revision procedures where other treatments or devices have failed; and treatment of fractures that are unmanageable using other techniques.

The ADVANCE® BIOFOAM® Tibial System and EVOLUTION® BIOFOAM® Tibial System implants are for cementless use only.

The DYNASTY® BIOFOAM® Acetabular Shell is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

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

The DYNASTY® BIOFOAM® Acetabular Shell is for uncemented use only.

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

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 EVOLUTION® Revision Tibial System.

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|---|---|
| **Submitted by:** | MicroPort Orthopedics Inc.<br>5677 Airline Rd, Arlington TN, 38002<br>Phone: 866-872-0211<br>Fax: 855-446-2247 |
| **Date:** | June 15, 2017 |
| **Contact Person:** | Grace Johnson-Bann<br>*Regulatory Affairs Specialist II* |
| **Proprietary Name:** | BIOFOAM® Additive Manufacturing (BIOFOAM® AM)<br>EVOLUTION® BIOFOAM® Tibial Base<br>ADVANCE® BIOFOAM® Tibial Base<br>DYNASTY® BIOFOAM® Acetabular Shell |
| **Common Name:** | Cementless Tibial Base, Uncemented Acetabular Shell |
| **Classification Name and Reference:** | 21 CFR 888.3565 - Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis<br>Class II<br>21 CFR 888.3353 – Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented<br>Class II |
| **Subject Product Code and Panel Code:** | Orthopedics/87/MBH, LZO |

**Predicate Device (EVOLUTION® BIOFOAM® Tibial Base, ADVANCE® BIOFOAM® Tibial Base):**

ADVANCE® Spiked Porous Tibial Base (K063128)

**Predicate Device (DYNASTY® BIOFOAM® Acetabular Shells):**

DYNASTY® Acetabular System (K122382)

**Reference Device:** EVOLUTION® BIOFOAM® Tibial System (K152298)

## DEVICE INFORMATION

### A. Intended Use

**ADVANCE® BIOFOAM® Tibial Bases and EVOLUTION® BIOFOAM® Tibial Bases**

The ADVANCE® BIOFOAM® and EVOLUTION® BIOFOAM® tibial bases are indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

1. Non-inflammatory degenerative joint disease: including osteoarthritis, traumatic arthritis, or avascular necrosis;
2. Inflammatory degenerative joint disease, including rheumatoid arthritis;
3. Correction of functional deformity;
4. Revision procedures where other treatments or devices have failed; and treatment of fractures that are unmanageable using other techniques.

The ADVANCE® BIOFOAM® Tibial System and EVOLUTION® BIOFOAM® Tibial System implants are for cementless use only.

**DYNASTY® BIOFOAM® Acetabular Shell**

The DYNASTY® BIOFOAM® Acetabular Shell is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

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

The DYNASTY® BIOFOAM® Acetabular Shell is for uncemented use only.

### B. Device Description

A process change is taking place to introduce BIOFOAM® Additive Manufacturing (BIOFOAM® AM) as an alternative to the currently manufactured BIOFOAM® material used as a porous coating. BIOFOAM® AM will be used as a porous coating for MicroPort Orthopedics' tibial bases and acetabular shells with the current BIOFOAM® material as a porous coating. The BIOFOAM® AM is a porous material manufactured from the same raw material as the predicate, Commercially Pure Titanium conforming to ASTM F67. The surface treatment of BIOFOAM® AM is identical to the predicate and helps to provide initial fixation. The structure and porosity of BIOFOAM® AM is designed to encourage bone apposition.

## C. Substantial Equivalence Information

The design features and materials of the subject devices are substantially equivalent to those of the predicate 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 device, as well. 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

The subject BIOFOAM® Additive Manufacturing (BIOFOAM® AM) was evaluated for static shear strength per ASTM F1044 and static tensile strength per ASTM F1147. A shear fatigue evaluation was also conducted per ASTM F1160. An abrasion evaluation was also performed.

Additionally, a stereological evaluation was completed per ASTM F1854.

The results from shear and tensile testing supported the conclusion that the subject BIOFOAM® AM has static shear strength and static tensile strength substantially equivalent to the predicate. The BIOFOAM® AM exhibited a static shear and tensile strength greater that required by the *FDA Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement*. The shear fatigue evaluation supported the conclusion that the shear fatigue strength of BIOFOAM® AM is substantially equivalent to the predicate. The results of the abrasion evaluation concluded that the subject material performs as well as the predicate and is expected to resist abrasive *in vivo* forces.

Bacterial Endotoxin Testing (BET) and the following validation activities for additive manufacturing were also performed:

- Validation of the build parameters
- Validation of the print chamber (orientation, location)
- Validation of the powder recycle
- Demonstration of residual powder removal

## E. Clinical Testing

Clinical data was not provided for the subject devices.

## F. Conclusion

The design features, materials information, predicate testing and analysis date provided in this premarket notification adequately support the substantial equivalence of the BIOFOAM® Additive Manufacturing (BIOFOAM® AM) material for use as an implant porous coating.