



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

MicroPort Orthopedics, Incorporated
Mr. Byron Ledbetter
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

November 16, 2015

Re: K152298

Trade/Device Name: EVOLUTION® BIOFOAM® Tibial System, ADVANCE®
BIOFOAM® Tibial System

Regulation Number: 21 CFR 888.3565

Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented
prosthesis

Regulatory Class: Class II

Product Code: MBH

Dated: August 11, 2015

Received: August 26, 2015

Dear Mr. Ledbetter:

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 Parts 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" (21CFR 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 yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K152298

Device Name
EVOLUTION® BIOFOAM® Tibial System

Indications for Use (Describe)

The EVOLUTION® BIOFOAM® Tibial System is 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 EVOLUTION® BIOFOAM® Tibial System is for use without bone cement.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Indications for Use

510(k) Number (if known)
K152298

Device Name
ADVANCE® BIOFOAM® Tibial System

Indications for Use (Describe)

The ADVANCE® BIOFOAM® Tibial System is 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 is for use without bone cement and is intended for use with EVOLUTION® and ADVANCE® modular keels.

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)

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EVOLUTION® BIOFOAM® Tibial System
 Traditional 510(k)
 Tab 006: 510(k) Summary of Safety and Effectiveness



510(k) Summary of Safety and Effectiveness

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® BIOFOAM® Tibial System.

Submitted by: MicroPort Orthopedics Inc.
 5677 Airline Rd, Arlington TN, 38002
 Phone: 866-872-0211
 Fax: 855-446-2247

Date: November 16, 2015

Contact Person: Byron Ledbetter
Regulatory Affairs Specialist II

Proprietary Name: EVOLUTION® BIOFOAM® Tibial System
 ADVANCE® BIOFOAM® Tibia

Common Name: Cementless Tibial Base

Classification Name and Reference: 21 CFR 888.3565 - Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis.

Subject Product Code and Panel Code: Class II
 Orthopedics/87/MBH

Predicate Device: ADVANCE® Porous Coated Spiked Tibial Base (K143366)

Reference Devices: ADVANCE® HA Coated Components (K043083)
 ADVANCE® Spiked Porous Tibial Base (K063128)
 EVOLUTION® MP Tibial Base (K093552, K102380)
 EVOLUTION® MP CS/CR Porous Femur (K140735)

DEVICE INFORMATION

A. Intended Use

EVOLUTION® BIOFOAM® Tibial System

The EVOLUTION® BIOFOAM® Tibial System is 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 EVOLUTION® BIOFOAM® Tibial System is for use without bone cement.

ADVANCE® BIOFOAM® Tibial System

The ADVANCE® BIOFOAM® Tibial System is 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 is for use without bone cement and is intended for use with EVOLUTION® and ADVANCE® modular keels.

B. Device Description

The EVOLUTION® BIOFOAM® Tibial System is a line extension of the EVOLUTION® MP Total Knee System product line. The device is an asymmetrical tibial base with a BIOFOAM® coating on the distal surface. The design features are summarized below:

Traditional 510(k)

Tab 006: 510(k) Summary of Safety and Effectiveness

- Manufactured from titanium alloy conforming to ASTM F620/F136 (forged/wrought)
- Available in 11 sizes, left and right
- Tibial base is available with and without holes for bone screws
- System includes 3 options of modular keels consisting of a two fin bullet-tip, a four fin bullet-tip and a four fin stem-accepting keel
- Compatible with 510(k) cleared EVOLUTION® Tibial Inserts, ADVANCE® Keels and ADVANTIM® Stems

The keel compatibility for the ADVANCE® BIOFOAM® Tibia is being expanded to include all keels subject to this 510(k). The subject design and indications remain identical according to K063128.

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 EVOLUTION® BIOFOAM® Tibial System was evaluated for fatigue strength per ASTM F1800 and 3-point stem fatigue. Results concluded that the subject tibial base is expected to perform as well or better than the predicate device in fatigue loading.

E. Clinical Testing

Clinical data was not provided for the subject devices.

F. Conclusion

The design features, materials information, predicate testing and analysis data provided in this premarket notification adequately support the substantial equivalence of the EVOLUTION® BIOFOAM® Tibial System.