MicroPort Orthopedics, Inc.
Grace Johnson-Bann
Sr. Regulatory Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

May 4, 2018

Re: K180317
Trade/Device Name: EVOLUTION® Knee Systems – MR Labeling, EVOLUTION® BIOFOAM® Tibial System, EVOLUTION® Revision Tibial System, EVOLUTION® Revision CCK 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, JWH
Dated: February 1, 2018
Received: February 5, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180317

Device Name
EVOLUTION® Knee Systems – MR Labeling, EVOLUTION® BIOFOAM® Tibial System, EVOLUTION® Revision Tibial System, EVOLUTION® Revision CCK System

Indications for Use *(Describe)*
The EVOLUTION® BIOFOAM® Tibial, EVOLUTION® Revision Tibial, and EVOLUTION® Revision CCK Systems 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 EVOLUTION® BIOFOAM® Tibial System implants are for cementless use only.

The EVOLUTION® Revision Tibial and EVOLUTION® Revision CCK Systems are for cemented 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.

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 EVOLUTION® Knee Systems MR Labeling.

Submitted by:	MicroPort Orthopedics Inc. 5677 Airline Rd, Arlington TN, 38002 Phone: 866-872-0211 Fax: 855-446-2247
Date:	May 2, 2018
Contact Person:	Grace Johnson-Bann *Sr. Regulatory Affairs Specialist*
Proprietary Name of Modified Device:	EVOLUTION® Knee Systems – MR Labeling EVOLUTION® BIOFOAM® Tibial System EVOLUTION® Revision Tibial System EVOLUTION® Revision CCK System
Common Name:	Cementless Knee Systems, Cemented Revision Knee Systems, MR Labeling
Classification Name and Reference:	21 CFR 888.3565 - Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis Class II 21 CFR 888.3560 – Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis Class II
Subject Product Code and Panel Code:	Orthopedics/87/MBH, JWH
Predicate Devices:	EVOLUTION® BIOFOAM® Tibial System (K152298) EVOLUTION® Revision Tibial System (K162026) EVOLUTION® Revision CCK System (K171389)
Reference Device:	MPO Total Knee Systems MR Labeling (K152631)

DEVICE INFORMATION

A. Intended Use

The EVOLUTION® BIOFOAM® Tibial System, EVOLUTION® Revision Tibial System, and EVOLUTION® Revision CCK System 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 EVOLUTION® BIOFOAM® Tibial System is for use without bone cement.

The EVOLUTION® Revision Tibial and CCK Systems are for cemented use only.

B. Device Description

A labeling change is taking place to include MR Conditional language and symbols to the implant components of the predicate device systems identified above. The changes only apply to the device labeling; therefore, the subject devices are identical to the predicate devices.

The non-clinical testing provided establishes the conditional safety and compatibility of the passive implants in a magnetic resonance (MR) environment. The subject devices include the following components and basic design features:

- Metal femoral components manufactured from cobalt chrome alloy
- Femoral revision accessories, including augments, manufactured from titanium alloy
- CCK tibial inserts manufactured from UHMWPE with locking screws and posts manufactured from titanium alloy
- Tibial bases manufactured from titanium alloy available in porous and non-porous versions
- Tibial revision accessories, including keels, augments, stem extensions, and adapters, manufactured from titanium alloy.
- Patellae manufactured from UHMWPE and cobalt chrome alloy

C. Substantial Equivalence Information

The scope of this Premarket Notification only includes labeling changes for the subject devices. The design features and materials of the subject devices are identical to those of the predicate devices. The indications for use of the subject devices are also identical those of 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**

Nonclincal testing was conducted to establish the conditional safety and compatibility of the passive implants in a magnetic resonance (MR) environment according to the recommendations provided in the Guidance for Industry and Food and Drug Administration Staff entitled "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment", issued by the US FDA on December 11, 2014. Testing was also conducted according to the following standards:

- NEMA MS 8-2008 *Characterization of the Specific Absorption Rate for Magnetic Resonance Imaging Systems*
- ASTM F2052-15 *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*
- ASTM F2119-07(2013) *Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants*
- ASTM F2182-11a *Standard Test Method For Measurement of Radio Frequency Induced Heating On Or Near Passive Implants During Magnetic Resonance Imaging*
- ASTM F2213-06(2011) *Standard Test Method For Measurement Of Magnetically Induced Torque On Medical Devices In The Magnetic Resonance Environment*
- ASTM F2503-13 *Standard Practice For Marking Medical Devices And Other Items For Safety In The Magnetic Resonance Environment*

The test determined the effects of MRI on the implants and the effects of the implants on the MR image quality. The tests evaluated the worst case components and constructs for RF heating, field interactions, and image artifacts. The testing concluded that there are no safety issues related to magnetic field interactions under the specific conditions identified in the labeling.

E. Clinical Testing

Clinical data was not provided for the subject devices.

F. Conclusion

The information provided in this Premarket Notification adequately supports the labeling change for the subject devices and the substantial equivalence of the subject devices to the predicate devices.