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

March 1, 2017

Microport Orthopedics, Inc.
Byron Ledbetter
Sr. Regulatory Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

Re: k162026
Trade/Device Name: Evolution Revision Tibial Base, Evolution Revision Tibial Block Augment, Evolution Revision Modular Keels, Evolution Revision Stem Adapters (offset And Extension), Evolution Revision Cemented Stem Extensions, Canal Filling Stem Extensions
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer demi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: January 27, 2017
Received: January 30, 2017

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 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,

Mark N. Melkerson -S

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)*

Device Name
EVOLUTION® Revision Tibial System

Indications for Use *(Describe)*

The EVOLUTION® Revision 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® Medial-Pivot Total Knee System Nonporous implants 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)

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.

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 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® Revision Tibial System.

Submitted by:	MicroPort Orthopedics Inc. 5677 Airline Rd, Arlington TN, 38002 Phone: 866-872-0211 Fax: 855-446-2247
Date:	January 26, 2017
Contact Person:	Byron Ledbetter *Sr. Regulatory Affairs Specialist*
Proprietary Name:	EVOLUTION® Revision Tibial System
Common Name:	Cemented Tibial Base
Classification Name and Reference:	21 CFR 888.3560 - Knee joint patellofemorotibial metal/polymer/metal semi-constrained cemented prosthesis. Class II
Subject Product Code and Panel Code:	Orthopedics/87/JWH
Predicate Device:	EVOLUTION® BIOFOAM® Tibial System (K152298)
Reference Devices:	ADVANCE® Total Knee System (K061223) ADVANCE® Modular Tibial Component System (K973524) ADVANCE® Revision (K990030) EVOLUTION® MP Total Knee System (K093552)

DEVICE INFORMATION

A. Intended Use

EVOLUTION® Revision Tibial System

The EVOLUTION® Revision 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® Medial-Pivot Total Knee System Nonporous implants are for cemented use only.

B. Device Description

The EVOLUTION® Revision Tibial System is being introduced to supplement MicroPort Orthopedics' knee product lines to provide revision surgery options with a cemented tibial base. The design features are summarized below:

- Manufactured from titanium alloy conforming to ASTM F620/F136 (forged/wrought)
- Available in 8 standard sizes, left and right
- Available in 3 plus sizes, left and right
- Tibial base has holes for augment attachment screws
- System includes tibial base, modular keels, block augments, stem adapters (offset & extension), stem extensions (cemented & canal-filling cementless) and stem caps (metallic and poly)

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® Revision Tibial System was evaluated for bacterial endotoxins and found to be less than the USP endotoxin limit of 20 EU/device. The testing established the subject product's non-pyrogenicity.

The subject EVOLUTION® Revision Tibial System was evaluated for fatigue strength via two methods: cantilever fatigue per ASTM F1800 and 3-point fatigue.

Additionally, the EVOLUTION® Revision Tibial System received static evaluation via axial distraction per ASTM F2009 and rotational distraction.

The results for fatigue strength concluded that the subject tibial base will have fatigue properties substantially equivalent to the predicate and is expected to perform as well or better than the predicate device in fatigue loading. The results for the static evaluation concluded that the subject tibial base will perform as intended.

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 EVOLUTION® Revision Tibial System.