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

MicroPort Orthopedics, Incorporated
Mr. Usman Rashid
Regulatory Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

March 23, 2016

Re: K152631
Trade/Device Name: MPO Total Knee Systems MR Labeling
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis.
Regulatory Class: Class II
Product Code: HRY, JWH, MBH
Dated: February 24, 2016
Received: February 26, 2016

Dear Mr. Rashid:

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

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)*
K152631

Device Name
MPO Total Knee Systems MR Labeling

Indications for Use *(Describe)*
MPO Total Knee Systems are indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:
1) noninflammatory 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.

ADVANCE® 913 Medial Pivot Tibial Base and Insert Components (not licensed for sale in Canada) are for use with bone cement.

Porous-Coated Total Knee Replacement Components are for use without bone cement.

The EVOLUTION® Total Knee System is 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)*

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 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the MicroPort Orthopedics Total Knee systems in an MRI environment.

Submitted by:	MicroPort Orthopedics Inc. 5677 Airline Rd Arlington, TN 38002 Phone: (866) 872-0211 Fax: (855) 446-2247
Date:	March 15, 2016
Contact Person:	Usman Rashid *Regulatory Affairs Specialist*
Proprietary Name of Modified Device:	MPO Total Knee Systems MR Labeling
Common Name:	MPO Total Knee Systems
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 21 CFR 888.3530 Knee joint Femorotibial Metal/Polymer Semi-Constrained Cemented Prosthesis Class II
Subject Product Code and Panel Code:	Orthopedics/87/MBH, JWH, HRY
Predicate Devices:	EVOLUTION® Revision Stemmed Femur (K142550) EVOLUTION® MP CS/CR Porous Femur & EVOLUTION® Adaptive CS and PS Inserts (K140735)

EVOLUTION® MP Adaptive PS Tibial Insert (K131679)

ADVANCE® TOTAL KNEE SYSTEM-PATELLA (K122218)

EVOLUTION® MP Adaptive CS Insert (K113325)

EVOLUTION® MP Total Knee System (K093552)

ADVANCE STATURE® Femoral Component (K063731)

ADVANCE® Spiked Porous Tibial Base (K063128)

ADVANCE® TOTAL KNEE SYSTEM (K061223)

ADVANCE® HA Coated Components (K043083)

ADVANCE® Double High Insert (K033890)

ADVANCE® Revision Product Line Extension (K990030)

ADVANCE® Modular Tibial Component (K973524)

ADVANCE® KNEE SYSTEM (K972626)

ADVANCE® TIBIAL COMPONENT (K960617)

ULTRACK TOTAL KNEE SYSTEM (K953439)

ORTHOLOC® ADVANTIM™ Tibial Base Component (K932858)

ORTHOLOC® ADVANTIM™ 5 Degree Tibial Stem (K930228)

SECOND GENERATION KNEE SYSTEM (K894334)

DEVICE INFORMATION

A. Intended Use

MicroPort Total Knee Systems are indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

1) noninflammatory 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.

ADVANCE® 913 Medial Pivot Tibial Base and Insert Components (not licensed for sale in Canada) are for use with bone cement.

Porous-Coated Total Knee Replacement Components are for use without bone cement.

The **EVOLUTION® Total Knee System** is for cemented use only.

B. Device Description

The subject devices for this submission are all the predicate devices listed above, which consists of implant components used in knee arthroplasty. The only changes to the subject devices are updates to their labeling. Specifically, the package inserts and package labels are being updated to include MR Conditional language and symbols. The subjects are identical to the predicates in all aspects except for the labeling updates. Testing is provided in this Traditional 510(k) that establishes the conditional safety and compatibility of the passive implants in a magnetic resonance (MR) environment. The basic design features are the following:

- Metal Femoral component manufactured from cobalt chrome alloy
- Femoral components available in porous and non porous versions
- Tibial inserts manufactured from UHMWPE
- Tibial bases manufactured from cobalt chrome alloy or titanium alloy
- Tibial bases available in porous and non porous versions
- All-poly patellae manufactured from UHMWPE
- Metal portion of metal backed patellae manufactured from titanium alloy

C. Substantial Equivalence Information

Since this submission is only regarding device labelling change, the design features and materials of the subject devices are identical to those of the predicate devices. The indications for use are identical to 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

Non clinical 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 document "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment" issued on December 11, 2014. Testing was also conducted according to the following standards:

ASTM F2052-14, "Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment";

ASTM F2119-7 "Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants";

ASTM F2503-13 "Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment";

ASTM F2182-11a "Standard Test Method for Measurement of Radio Frequency Induced Heating near Passive Implants During Magnetic Resonance Imaging"

The tests determined the effects of the MRI on the implants, and the effects of the implants on the 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 specific conditions identified in the labeling.

E. Clinical Testing

Clinical data was not provided for the subject devices.

F. Conclusion

All the information provided in this submission adequately supports the substantial equivalence of the labelling change.