May 16, 2019

MicroPort Orthopedics, Inc.
Ryan Ross
Manager, Regulatory Affairs
5677 Airline Road
Arlington, Tennessee 38002

Re: K182251
Trade/Device Name: EVOLUTION® NitrX™ Medial-Pivot Knee
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: August 17, 2018
Received: August 20, 2018

Dear Ryan Ross:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

FOR CAPT Raquel Peat, PhD, MPH, USPHS
Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*

K182251

Device Name
EVOLUTION® NitrX™ Medial-Pivot Knee

Indications for Use *(Describe)*

The EVOLUTION® NitrX™ Medial-Pivot Knee 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)

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 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® NitrX™ Medial-Pivot Knee.

Submitted by:	MicroPort Orthopedics Inc. 5677 Airline Rd, Arlington TN, 38002 Phone: 866-872-0211 Fax: 855-446-2247
Date:	May 16, 2019
Contact Person:	Ryan Ross *Manager, Regulatory Affairs*
Proprietary Name:	EVOLUTION® NitrX™ Medial-Pivot Knee
Common Name:	Cemented Tibial Base Cemented Femur
Classification Name and Reference:	21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis Class II
Subject Product Code and Panel Code:	Orthopedics/87/JWH
Predicate Device:	EVOLUTION® Medial Pivot Total Knee System (K093552, K102380)
Reference Device:	Foundation® Knee System with TiNbN Coating, Foundation® PS Knee System with TiNbN Coating, 3DKnee™ System with TiNbN Coating (K122239)
Reference Device:	EVOLUTION® Knee Systems – MR Labeling (K180317)

DEVICE INFORMATION

A. Intended Use

The EVOLUTION® NitrX™ Medial-Pivot Knee 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® NitrX™ Medial-Pivot Knee is a line extension of the EVOLUTION® MP Total Knee System product line. The device is intended to be used as a medial pivot option in total knee arthroplasty (TKA). The subject device is composed of a femoral component to replace the distal surface of the patient's natural femur and a tibial baseplate component to replace the proximal surface of the patient's natural tibia. The design features are summarized below:

- Manufactured from Cobalt Chrome Alloy
- Coated with Titanium Niobium Nitride
- Sizes 1-8, left and right

C. Substantial Equivalence Information

The design features and materials of the subject devices are substantially equivalent to those of the predicate/reference devices. The indications for use are identical to the predicate device. The fundamental scientific technology of the modified devices has not changed relative to the predicate device. 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

Nonclinical testing performed on the subject devices included:

- Biocompatibility evaluation/testing
- Tibial baseplate component fatigue testing
- Wear analysis (Mode 1 and aggressive Mode 3)
- Morphological analysis
- Metal ion analysis

Additionally, nonclinical predicate test results were used to support the subject due to equivalencies between devices. Predicate testing included:

- Range of motion analysis
- Stability/Constraint
- Contact area/stress
- MR Assessments- Field Interactions, Torque, Displacement, RF Heating
- Gravimetric Analysis
- Bioburden Testing

E. Clinical Testing

Clinical data was not provided for the subject devices.

F. Conclusion

The indications for use and fundamental scientific technology of the subject devices are identical to the predicate devices. Design features, materials information, predicate testing and analysis data provided in this premarket notification adequately support the substantial equivalence of EVOLUTION® NitrX™ Medial-Pivot Knee.