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 Inc. August 8, 2017
Matt Paul
Regulatory Affairs Project Manager
5677 Airline Road
Arlington, Tennessee 38002

Re: K171389
Trade/Device Name: EVOLUTION Revision CCK System
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: May 10, 2017
Received: May 11, 2017

Dear Matt Paul:

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)*

K171389

Device Name
EVOLUTION® Revision CCK System

Indications for Use *(Describe)*

The EVOLUTION® Revision CCK 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.

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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 EVOLUTION® Revision CCK System.

Submitted by:	MicroPort Orthopedics Inc. 5677 Airline Rd, Arlington TN, 38002 Phone: 866-872-0211 Fax: 855-446-2247
Date:	August 2, 2017
Contact Person:	Matt Paul
Proprietary Name:	EVOLUTION® Revision CCK System
Common Name:	Total knee implant
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:	K093552 EVOLUTION® MP Total Knee System K142550 EVOLUTION® MP Revision Femur K162026 EVOLUTION® Revision Tibial System K093552 EVOLUTION® MP Total Knee System

Reference Devices:

Femoral Component:
K990030 ADVANCE® Revision (CCK System)
K142550 EVOLUTION® MP Revision Femur
K063731 ADVANCE® STATURE Femoral Component
K901992 Whiteside Ortholoc Modular Post. Stab. Knee System
K932677 AXIOM Total Knee System
K863668/K871769 Omnifit Series I Total Knee System
K892800/K895639/K911572/K930831 MG II Total Knee System – Flat, AP Lipped
K862837 Omnifit Series I Total Knee System
K882322/K896542/K901457/K914072 Continuum (CKS) Primary Total Knee System
K953439 Ultrack (ADVANCE®) Total Knee
K972626 ADVANCE® Knee System

Femoral Augment:
K990030 ADVANCE® Revision CCK System

Tibial Insert:
K093552 EVOLUTION® MP CS/CR and PS Tibial Inserts
K990030 ADVANCE® Revision CCK Tibial Insert
K162026 EVOLUTION® Revision Tibial Base and Screw
K973524 ADVANCE® Modular Tibial Component, Screw
K063731 ADVANCE® STATURE Femoral Component
K953439 Ultrack (ADVANCE®) Total Knee System
K932677 AXIOM Total Knee System
K972770 ADVANCE® Ultra-Congruent Tibial Insert
K102380 EVOLUTION® MP Total Knee System
K152298 EVOLUTION® BIOFOAM Tibial Base
K063128 ADVANCE® Spiked Porous Tibial Base

DEVICE INFORMATION

A. Intended Use

The EVOLUTION® Revision CCK 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

EVOLUTION® Revision CCK (Constrained Condylar Knee) is being introduced to supplement MicroPort Orthopedics' knee product lines to provide options in the case of revision or complex primary total knee replacements. The design features are summarized below:

- Components manufactured from cobalt chrome alloy, titanium alloy, and UHMWPE conforming to ASTM F75, F136, and F648, respectively
- Available in 8 standard sizes, left and right
- Available in 2 plus sizes, left and right
- System includes femoral component, augments, stem offset adapters, tibial insert and stem cap

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. 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 CCK system was evaluated for bacterial endotoxins and found to be less than the USP endotoxin limit of 20 EU/device.

The subject EVOLUTION® Revision CCK system was evaluated for patellofemoral contact area, tibiofemoral contact area, tibial post shear fatigue, taper disassembly, and taper fatigue.

Results for patellofemoral contact area testing concluded the subject EVOLUTION® Revision CCK system to perform as well as the predicate K990030 implants in respect to measured contact area. Results for tibiofemoral contact area testing concluded the subject EVOLUTION® Revision CCK System to possess greater maximum contact area than the predicate K990030 implants. Results of tibial post shear fatigue testing concluded the subject EVOLUTION® Revision CCK system to demonstrate greater fatigue resistance than the predicate K990030. Results of taper disassembly testing indicate the subject EVOLUTION® Revision CCK system will withstand typical *in vivo* disassociation forces as reported in peer reviewed literature. Results of taper fatigue testing demonstrated the subject EVOLUTION® Revision CCK Femoral constructs to achieve taper disassembly values greater than those of the predicate K162026.

E. Clinical Testing

Clinical data was not provided for the subject devices.

F. Component and Accessory Compatibility

The subject devices are compatible with the following previously cleared MicroPort Orthopedics products.

Femoral

K162026 EVOLUTION® Revision Stem Extensions
K162026 EVOLUTION® Revision Straight Stem Extension Adapters
K142550 EVOLUTION® Revision Distal and Posterior Femoral Augments

Patella

K122218 ADVANCE® Patella
K953439 ADVANCE® Patella

Tibial

K162026 EVOLUTION® Revision Tibial Base
K162026 EVOLUTION® Revision Tibial Augments
K162026 EVOLUTION® Revision Modular Keel
K162026 EVOLUTION® Revision Tibial Stem Offset Adapters
K162026 EVOLUTION® Revision Straight Stem Extension Adapters
K162026 EVOLUTION® Revision Stem Extensions

The EVOLUTION® Revision CCK System instrumentation includes reamers, trials, guides, broaches, bushings, spacers, drivers, and clamps.

G. Conclusion

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