December 6, 2018

MicroPort Orthopedics Inc.
Hunter Williams
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

Re: K182125
Trade/Device Name: EVOLUTION Stemmed CS Femur
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 3, 2018
Received: August 6, 2018

Dear Hunter Williams:

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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2018.12.06 13:43:01 -05'00'

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)*
K182125

Device Name
EVOLUTION® Stemmed CS Femur

Indications for Use *(Describe)*
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.

Non-porous MicroPort total knee replacement 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® Stemmed CS Femur:

Submitted by:	MicroPort Orthopedics Inc. 5677 Airline Rd, Arlington TN, 38002 Phone: 866-872-0211 Fax: 855-446-2247
Date:	November 8, 2018
Contact Person:	Hunter E. Williams *Regulatory Affairs Specialist II*
Proprietary Name:	EVOLUTION® Stemmed CS Femur
Common Name:	Stemmed Femoral System
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® MP Revision Femoral System (K142550)
Reference Devices:	EVOLUTION® Revision CCK System (K171389) EVOLUTION® MP CS/CR Non-Porous Femur (K093552, K102380)

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.

Non-porous MicroPort total knee replacement implants are for cemented use only.

B. Device Description

The EVOLUTION® Stemmed CS Femur is a line extension of the EVOLUTION® revision knee system product line. The device is a stemmed distal femoral knee joint replacement implant design to address bone-on-bone bearing conditions in a patient's knee where there is also a lack of bone stock or quality, but intact and sufficient collateral ligaments. An optional polyethylene stem cap designed to obstruct bone cement migration into the trunnion is packaged with the subject femoral component in the event no stem extension or adapter is used. The design features are summarized below:

- Manufactured from Cobalt Chrome Alloy
- CS design, sizes 1-8, left and right
- Compatible with 510(k) cleared EVOLUTION® Revision Stem Extensions, EVOLUTION® Revision Offset Adapters, EVOLUTION® Stem Adapters, EVOLUTION® Revision Femoral Augments, EVOLUTION® MP CS Tibial Inserts, EVOLUTION® Adaptive CS Tibial Inserts, and ADVANCE® Patella Components.

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

Non clinical predicate test results were used to support the subject due to equivalencies between devices. Predicate testing included:

-Range of Motion analysis
-Tibiofemoral and patellofemoral Stability/Constraint
-Tibiofemoral and patellofemoral contact area/stress
-Component Interlock Strength
-MR Assessments- Field Interactions, Torque, Displacement, RF Heating

More information on predicate test results supporting subject device can be found in **Tab 013 Executive Summary** of the 510(k) submission.

E. Clinical Testing

Clinical data was not provided for the subject devices.

F. Biocompatibility

The intended patient contact and materials used in the subject implant devices are identical to those of the predicate devices. No subject implants use colorants. Therefore, biocompatibility testing was not completed on the subject devices.

G. Component and Accessory Compatibility

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

Component	510(k)
Stem Extensions	
EVOLUTION® Revision Canal Filing and Cemented Stem Extensions	K162026
Offset Adapters	
EVOLUTION® Revision Femoral Offset Adapters	K171389
Stem Adapters	
EVOLUTION® Revision Stem Adapters	K162026
Femoral Augments	
EVOLUTION® Revision Femoral Augments	K142550, K171389
Tibial Inserts	
EVOLUTION® MP CS Insert	K093552
EVOLUTION® Adaptive CS Inserts	K113325, K140735
Patella Components	
ADVANCE® All-Poly Onlay Patella, Tri-Peg	K122218, K953439
ADVANCE® All-Poly Onlay Patella, Single-Peg	K122218, K953439
ADVANCE® All-Poly Recessed Patella, Single-Peg	K953439
ADVANCE® Onlay Metal Back Patella	K122218

The EVOLUTION® Stemmed CS Femur instrumentation includes guides, trials, and burrs. The subject devices also utilize instrumentation previously cleared in EVOLUTION® REVISION CCK System (K171389) and EVOLUTION® Revision Tibial System (K162026).

H. Conclusion

The intended use, 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® Stemmed CS Femur.