October 31, 2023

MicroPort Orthopedics Inc.
Jonas Susaraba
Regulatory Affairs Specialist II
5677 Airline Rd
Arlington, Tennessee 38002

Re: K231947
Trade/Device Name: EVOLUTION® Cement Keel
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: September 12, 2023
Received: September 14, 2023

Dear Jonas Susaraba:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lixin Liu -S

Lixin Liu, Ph.D.
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231947

Device Name
EVOLUTION® Cement Keel

Indications for Use *(Describe)*
The EVOLUTION® Cement Keel 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® Cement Keels 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.

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® Cement Keel.

Submitted by:	MicroPort Orthopedics Inc. 5677 Airline Rd, Arlington TN, 38002 USA Phone: 866-872-0211 Fax: 855-446-2247
Date:	October 30, 2023
Contact Person:	Jonas Susaraba
Proprietary Name:	EVOLUTION® Cement Keel
Common Name:	Modular Keel
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® Revision Tibial System**, K162026

Reference Devices: **N/A**

DEVICE INFORMATION

A. Intended Use/Indications for Use Statement

The EVOLUTION® Cement Keel 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® Cement Keels are for cemented use only.

B. Device Description

MicroPort Orthopedics Inc. is seeking clearance to introduce the subject device, the EVOLUTION® Cement Keel, a line extension to the predicate EVOLUTION® Revision Tibial System cleared in K162026. It is a smaller, lower-profile size compared to the existing predicate Modular Keels, is manufactured from Ti6Al4V alloy conforming to ASTM F136, and is compatible with the same tapers as the predicate. The intended use of the subject modular keel is identical to the predicate, which is to provide optional rotational stability and added fixation to the compatible tibial bases.

C. Substantial Equivalence Information

The indications for use and the technological characteristics of the subject device are similar but not the same to the predicate device. The design features of the subject device are substantially equivalent to those of the predicate devices and do not create any new worst-case scenarios. The safety and effectiveness of the subject device are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this premarket notification submission.

D. Nonclinical Testing

A dimensional comparison analysis was performed to compare the subject device to the predicate device. Due to dimensional equivalency between the two devices, predicate axial and rotational distraction testing submitted in K162026 were leveraged to support the subject device. Justifications were leveraged for biocompatibility, sterility and shelf life based on equivalency to the predicate device.

MRI safety evaluation per ASTM F2182-19, FDA Guidance “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment”, issued May 20, 2021, FDA Guidance for "Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices" issued March 2016, ASTM F2182-11a, ASTM F2181-11, ASTM F2052-15, ASTM F2213-17, and ASTM F2119-07 (reapproved 2013).

E. Clinical Testing

Clinical data was not provided for the subject devices.

F. Biocompatibility

Biocompatibility testing was not needed because the subject device does not introduce new or modify existing biocompatibility risk. The subject implant materials are identical to the final sterilized materials of the predicate device for formulation, processing and sterilization. Additionally the overall geometry and site of application are the same.

G. Conclusion

Based on the design features, the use of established well-known materials, feature comparisons, indications for use, principle of operations and results of the nonclinical testing, the subject EVOLUTION® Cement Keel has been shown to be substantially equivalent to the legally marketed predicate devices cited in this premarket notification.