January 5, 2022

MicroPort Orthopedics Inc.
Gillen Gonzales
Regulatory Affairs Specialist I
5677 Airline Road
Arlington, Tennessee 38002

Re: K213817
Trade/Device Name: MPO Knee Instruments; MPO PROPHECY Knee Instruments
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH, OOG
Dated: December 6, 2021
Received: December 7, 2021

Dear Gillen Gonzales:

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/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 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 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,

Ting Song, PhD
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.

Submission Number *(if known)*

K213817

Device Name

MPO Knee Instruments;
MPO PROPHECY Knee Instruments

Indications for Use *(Describe)*

MicroPort knee instruments are accessory devices and are intended to be used to assist in the implantation of MicroPort Total Knee Systems in their cleared Indications for Use as provided below:

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.

Porous coated MicroPort total knee replacement implants, including ADVANCE® BIOFOAM® Tibial System and EVOLUTION® BIOFOAM® Tibial System implants, are for use without bone cement.

MicroPort's PROPHECY® Pre-Operative Navigation Alignment Guides are intended to be used as patient-specific surgical instrumentation to assist in the positioning of total knee replacement components intra-operatively and in guiding the marking of bone before cutting. The PROPHECY® Pre-Operative Navigation Alignment Guides are intended for use with MicroPort's ADVANCE® and EVOLUTION® Total Knee Systems and their cleared indications for use, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans. The PROPHECY® Pre-Operative Navigation Alignment Guides are intended for single 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

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 MPO Knee Instruments Reprocessing Change.

Submitted by:	MicroPort Orthopedics Inc. 5677 Airline Road, Arlington, TN 38002 Phone: 866-872-0211 Fax: 855-446-2247
Date:	December 6, 2021
Contact Person:	Gillen Gonzales *Regulatory Affairs Specialist I*
Proprietary Name:	MPO Knee Instruments; MPO PROPHECY Knee Instruments
Common Name:	Orthopedic Surgical Instruments
Classification Name and Reference:	21 CFR888.3565 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
Subject Product Code and Panel Code:	Orthopedics/87/ MBH, JWH, OOG
Predicate Devices:	EVOLUTION® MP CS/CR Porous Femur (K140735) EVOLUTION® Adaptive CS and PS Inserts (K140735) EVOLUTION® MP Revision Femoral System (K142550) ADVANCE® Porous Coated Spiked Tibial Base (K143366) EVOLUTION® BIOFOAM® Tibial System (K152298) ADVANCE® BIOFOAM® Tibia (K152298) EVOLUTION® Revision Tibial System (K162026) EVOLUTION® Revision CCK System (K171389) EVOLUTION® Stemmed CS Femur (K182125) PROPHECY® ADVANCE® Navigation Guides (K093405) PROPHECY® EVOLUTION® Navigation Guides (K103598)

DEVICE INFORMATION

A. Device Description

The device modification consists of an alteration to the sterilization instructions for FDA-cleared MicroPort Orthopedics' (MPO) non-sterile knee orthopedic joint replacement instruments. The subject instruments are part of MicroPort Orthopedics' 510(k)-cleared knee product lines and are required to facilitate total knee arthroplasty procedures. The modification will allow the option to sterilize the subject instruments using an FDA-cleared containment device. The subject devices will be placed in an FDA-cleared containment device, which will be double-wrapped in an FDA-cleared CSR wrap or similar type nonwoven, medical grade wrapping material, and then steam sterilized.

The modified sterilization process of the subject instruments was successfully challenged and validated through worst-case load configurations using an FDA-cleared containment device. The intended use and sterilization parameters, such as cycle, temperature, and exposure time, remain identical to the predicate devices.

B. Intended Use

MicroPort knee instruments are accessory devices and are intended to be used to assist in the implantation of MicroPort Knee Systems in their cleared Indications for Use as provided below:

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;
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C. Technological Characteristics Comparison

MicroPort subject non-sterile knee orthopedic joint replacement instruments were successfully validated and sterilized using an FDA-cleared containment device. MicroPort non-sterile orthopedic joint replacement instruments are able to withstand the reported sterilization cycles and achieve sufficient device sterility.

D. Nonclinical Testing

Provided below is a summary table of the non-clinical testing that were performed using the subject device. The result demonstrated that the subject device nonclinical test results met the acceptance criteria of the standards.

- Steam Sterilization Validation of MicroPort orthopedic joint replacement instruments using FDA-cleared containment device (single-level tray) per AAMI ST77:2013
- Steam Sterilization Validation of MicroPort orthopedic joint replacement instruments using FDA-cleared containment device (double-level tray) per AAMI ST79:2017
- Vibration Test of MicroPort orthopedic joint replacement instruments using FDA-cleared containment device per ISTA 2A.

E. Clinical and Animal Testing

No clinical or animal testing were required.

F. Conclusions

The sterilization of the subject devices is substantially equivalent to the predicate devices. The safety and effectiveness of the modified sterilization method of the subject devices is adequately supported by the substantial equivalence information, materials information, and design control summaries data provided within this Premarket Notification. Validation testing and analysis data adequately support the substantial equivalence of MPO Knee Instruments Reprocessing Change.