January 5, 2022

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

Re: K213816
Trade/Device Name: MPO Hip Instruments
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, JDI, LPH, MBL, KWL, KWY
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,

Limin Sun, Ph.D.
Acting 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)*

K213816

Device Name

MPO Hip Instruments

Indications for Use *(Describe)*

MicroPort hip instruments are accessory devices and are intended to be used to assist in the implantation of MicroPort Hip Systems in their cleared indications for use.

MicroPort total hip systems are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients:
1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2) inflammatory degenerative joint disease such as rheumatoid arthritis;
3) correction of functional deformity; and,
4) revision procedures where other treatments or devices have failed

Rough grit blast surfaces and the hydroxyapatite and titanium plasma spray coatings applied to implant surfaces are intended for uncemented arthroplasty.
Shells with BIOFOAM® metal foam coating are intended only for uncemented arthroplasty.
LINEAGE® and DYNASTY® modular shells with porous metal bead coating are intended only for uncemented arthroplasty.
PRIME shells are intended only for uncemented arthroplasty.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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 Hip Instruments Reprocessing Change.

Submitted by:	MicroPort Orthopedics Inc. 5677 Airline Road, Arlington, TN 38002 Phone: 866-872-0211 Fax: 855-446-2247
Date:	January 4, 2022
Contact Person:	Gillen Gonzales *Regulatory Affairs Specialist I*
Proprietary Name:	MPO Hip Instruments
Common Name:	Orthopedic Surgical Instruments
Classification Name and Reference:	21 CFR 888.3353 Hip joint metal/ceramic/polymer semi constrained cemented or nonporous, uncemented prosthesis - Class II (Primary) 21 CFR 888.3350 Hip joint metal/polymer semi-constrained cemented prosthesis- Class II 21 CFR 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis - Class II 21 CFR 888.3360 Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis - Class II 21 CFR 888.3390 Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis - Class II
Subject Product Code and Panel Code:	Orthopedics/87/ LZO (Primary), JDI, LPH, MBL, KWL, KWY
Primary Predicate Device:	PROFEMUR® TL CLASSIC LONG NECK HIP STEMS (K140676)
Predicate Devices:	PROFEMUR® RENAISSANCE® CLASSIC LONG NECK HIP STEMS (K141235) PROFEMUR® Preserve Size 1-3 Hip Stems (K150133)

PROFEMUR® Preserve Classic Stem (K150302)
Prime Acetabular Cup System (K170444)
MicroPort CoCr Femoral Heads (K190123)
PROFEMUR® TL2 Stems (K191632)
PROFEMUR® GLADIATOR® Cemented Classic Stem (K201519)

DEVICE INFORMATION

A. Device Description

The device modification consists of an alteration to the sterilization instructions for FDA-cleared MicroPort Orthopedics' (MPO) non-sterile hip orthopedic joint replacement instruments. The subject instruments are part of MicroPort Orthopedics' hip product lines and are required to facilitate total hip 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 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 hip instruments are accessory devices and are intended to be used to assist in the implantation of MicroPort Hip Systems in their cleared indications for use.

MicroPort total hip systems are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

Indications for Use

1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2) inflammatory degenerative joint disease such as rheumatoid arthritis;
3) correction of functional deformity; and,
4) revision procedures where other treatments or devices have failed

Rough grit blast surfaces and the hydroxyapatite and titanium plasma spray coatings applied to implant surfaces are intended for uncemented arthroplasty.

Shells with BIOFOAM® metal foam coating are intended only for uncemented arthroplasty.

LINEAGE® and DYNASTY® modular shells with porous metal bead coating are intended only for uncemented arthroplasty.

PRIME shells are intended only for uncemented arthroplasty.

C. Technological Characteristics Comparison

MicroPort non-sterile hip 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 are the non-clinical tests 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 Hip Instruments Reprocessing Change.