MicroPort Orthopedics Inc.
Tejas Patel
Senior Regulatory Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

July 15, 2019

Re: K190123
Trade/Device Name: MicroPort CoCr Femoral Heads
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH
Dated: June 17, 2019
Received: June 18, 2019

Dear Tejas Patel:

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,

FOR Vesa Vuniqi
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190123

Device Name

MicroPort CoCr Femoral Heads

Indications for Use *(Describe)*

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 with the following conditions:

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.

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

January 24, 2019

I. Company: MicroPort Orthopedics Inc.
5677 Airline Road
Arlington, TN 38002
Telephone Number: (901) 290-5175

II. Contact: Tejas Patel
Senior Regulatory Affairs Specialist
Telephone number: (901) 290-5175
Email: tejas.patel@ortho.microport.com

III. Trade Name: MicroPort CoCr Femoral Heads
Classification: Class II
Classification Name:
Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR 888.3358)
Subject Product Code and Panel Code:
Orthopedics/87/ LPH

IV. Predicate Device:

- TRANSCEND® Articulation System (K170444, SE 06/26/2017)

This predicate has not been subject to a design-related recall.

V. Reference Device:

- SLT Femoral Head (K932222, SE 05/27/1994)
- MicroPort Orthopedics Total Hip Systems MR Labeling (K173898, SE 09/20/2018)
- APEX Modular Head (K101575, SE 06/30/2010)
- Whiteside Ortholoc Total Hip Femoral (K842559, SE 12/20/1984)
- Depuy M-Spec 36mm Femoral Heads (K120599, SE 04/30/2013)

VI. Device Description:

The subject MicroPort Orthopedics (MPO) CoCr femoral heads are spherical in shape and manufactured from low carbon cobalt chromium molybdenum alloy. The outer surface of the subject devices articulates against a polyethylene acetabular liner. The subject femoral heads possess an outer articulating surface finish of ≤3µin. The subject femoral heads are provided sterile. The proposed MPO femoral heads fill a gap in the current CoCr head offering. MicroPort CoCr heads are currently offered with short (S), medium (M), long (L) and extra-long (XL) offset for 32mm and 36mm diameter heads. The proposed new product offering in extra short (XS) and extra extra - long (XXL) offset

will bring the CoCr heads offering into alignment with the current market presence of 32mm and 36mm heads.
The sole purpose for this traditional 510(k) is to seek clearance for the additional offering (XS and XXL) of the CoCr femoral heads in 32mm and 36mm sizes.

VII. Indications for Use:

The MicroPort total hip systems are indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankyloses, protrusio acetabuli, and painful hip dysplasia.
2. Inflammatory degenerative joint disease such as rheumatoid arthritis.
3. Correction of functional deformity.
4. Revision procedures where other treatments or devices have failed.

VIII. Comparison of Technological Characteristics with the Predicate devices:

As established in this submission, the subject MPO CoCr femoral heads are substantially equivalent to the identified predicate devices cleared by the FDA for commercial distribution in the United States. The subject devices were shown to be substantially equivalent and have equivalent technological characteristics to their predicate devices through comparison in areas including design, intended use, material composition, operational principles and function.

IX. Discussion of the Non-clinical Testing/Performance Data:

Mechanical Testing:
MicroPort has evaluated the subject devices to demonstrate substantial equivalence to the identified predicate devices. Design verification testing for the subject implants was completed in accordance with

- ASTM F1714 - 96(2018) - Standard Guide for Gravimetric Wear Assessment of Prosthetic Hip-Designs in Simulator Devices
- ASTM F2003 - 02(2015) Standard practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma Irradiation in Air
- ASTM F1877-16, Standard Practice for Characterization of Particles, ASTM International, West Conshohocken, PA, 2016
- ISO 14242-2 (2016): Implants for surgery -- Wear of total hip-joint prostheses -- Part 2: Methods of measurement.
- ISO 14242-3 (2009): Implants for surgery -- Wear of total hip-joint prostheses -- Part 3: Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test.

The tests completed were:

- Wear Testing
- Frictional Torque Test

The mechanical testing verifies that the subject components are substantially equivalent to the predicate devices currently on the market and have met all mechanical testing requirements based on the worst case construct testing.

Non-Pyrogenicity Endotoxin Testing:

The bacterial endotoxin test, also known as Limulus amebocyte lysate (LAL) test, was performed utilizing worst case subject implants to verify that the subject implants meet the 20 endotoxin units (EU)/device pyrogen limit specification. Testing was successfully performed and it was confirmed that the subject implants meet the 20 EU/device testing limit for general medical devices that are implanted as outlined in ANSI/AAMI ST72, Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing and USP <161>, Medical Devices – Bacterial Endotoxin and Pyrogen Tests.

X. Component and Accessory Compatibility:

Table #1 and #2 show the compatibility of the subject devices with previously cleared MicroPort Orthopedics products.

Table #1: Compatible Shells and Liners, Including 510(k) information

510(k)	Device Name
K061547	DYNASTY® Beaded Shells and Liners
K062693	GLADIATOR™ Bipolar Shells and Liners
K070785	DYNASTY® Beaded Shells and Liners
K082924	DYNASTY® BIOFOAM® Shells and Liners
K122382	DYNASTY® BIOFOAM® Shells and Liners
K142119	PROCOTYL® L Beaded Shells and Liners
K170444	PROCOTYL® PRIME Shell and Liners
K171181	PROCOTYL® PRIME E-CLASS™ Shells and Liners
K180798	Prime Acetabular Cup System
K181598	Prime E-Class XLPE Liner

Table #2: Compatible Femoral Components, Including 510(k) Information

510(k)	Device Name
K003016	PRO-FEMUR R
K012091	PRO-FEMUR
K021346	STEM HIP REPLACEMENT SYSTEM
K041114	PROFEMUR TAPERED HIP STEM
K041586	PROFEMUR S HIP STEM
K051995	PROFEMUR RENAISSANCE HIP STEM

K052915	PROFEMUR XTR HIP STEM
K053588	PROFEMUR LX HIP STEM
K060358	PROFEMUR TL HIP STEM
K080663	PROFEMUR LX REVISION 5/8 COATED HIP STEM
K081090	PROFEMUR LX 5/8 COATED HIP STEM
K091423 K100866	PROFEMUR HIP SYSTEM MODULAR NECKS
K110399	GLADIATOR PLASMA CLASSIC HIP STEM
K111698	PROFEMUR(R) E CEMENTLESS HIP STEM
K111699	PROFEMUR(R) Z TITANIUM PLASMA SPRAYED HIP STEM
K111910	GLADIATOR HIP STEM
K112080	PRESERVE HIP STEM
K112150	PROFEMUR GLADIATOR HA HIP STEM
K121221	PROFEMUR Z REVISION HIP STEM
K123434	PROFEMUR Z CLASSIC STEM
K123688	PROFEMUR TL CLASSIC STEM
K130984	PROFEMUR RENAISSANCE CLASSIC STEM
K140676	PROFEMUR TL CLASSIC LONG NECK HIP STEMS
K141235	PROFEMUR RENAISSANCE CLASSIC LONG NECK HIP STEMS
K150133	PROFEMUR PRESERVE SIZE 1-3 HIP STEMS
K150302	PROFEMUR PRESERVE CLASSIC STEM

XI. Conclusion:

Based on the design features, the use of established well-known materials, feature comparisons, indications for use, and results of the mechanical testing, the subject MicroPort CoCr femoral heads have shown to be substantially equivalent to the legally marketed predicate devices cited in this summary.