DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 26, 2017

MicroPort Orthopedics Inc.
Kaitlin Grove
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

Re: K170444
Trade/Device Name: PROCOTYL® PRIME Acetabular Cup System
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, LZO, HWC
Dated: May 24, 2017
Received: May 25, 2017

Dear Kaitlin Grove:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
PROCOTYL® PRIME Acetabular Cup System

Indications for Use *(Describe)*
The PROCOTYL® PRIME Acetabular Cup System is 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.

Shells with BIOFOAM® metal foam coating 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."

MicroPort Orthopedics Inc.

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 807.92, this information serves as a Summary of Substantial Equivalence for the use of the PROCOTYL® PRIME Acetabular Cup System.

Submitted by:	MicroPort Orthopedics Inc. 5677 Airline Rd, Arlington TN, 38002 Phone: 866-872-0211 Fax: 855-446-2247
Date:	June 22, 2017
Contact Person:	Kaitlin Grove *Regulatory Affairs Specialist II*
Proprietary Name:	PROCOTYL® PRIME Acetabular Cup System
Common Name:	acetabular shell, acetabular liner and bone screw
Classification Name and Reference:	21 CFR 888.3358 - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis - Class II 21 CFR 888.3353 - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis – Class II 21 CFR 888.3040 - Smooth or threaded metallic bone fixation fastener - Class II
Subject Product Code and Panel Code:	Orthopedics/87/LPH, LZO, HWC
Predicate Device:	LINEAGE® Acetabular System (K002149 – Shell) LINEAGE® Acetabular System (K052026 - Liner) Cancellous Bone Screw (K864626) DYNASTY® Acetabular System (K082924 Shells; K002149, K061547, K070785, K082924 Liners) Zimmer Biomet Trilogy Acetabular Cup System (K934765, K953490) Depuy Pinnacle 100 Shell (K090998)

MicroPort Orthopedics Inc.

DEVICE INFORMATION

A. Intended Use

The PROCOTYL® PRIME Acetabular Cup System is 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

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

Similar to the explanation that was given in K111699 for MicroPort hip stems, these indications were stated as five (5) items (cleared with K971429, K002149 and K043099) and were eventually consolidated to four (4) items (as first cleared with hip stem K041114). The current indications are applied to all MicroPort polyethylene total acetabular systems and have been cleared in K052026, K061547, K070785, K072656, K082924, K122382, K130376, K140043.

B. Device Description

The PROCOTYL® PRIME Acetabular Cup System includes acetabular shells, acetabular liners, and optional cancellous bone screws. The design features are summarized below:

- Acetabular Shells
  - Manufactured from titanium alloy
  - BIOFOAM® coated
  - Available in Solid or Quad configurations
  - Outer Diameter sizes 42mm to 68mm in 2mm increments
- Acetabular Liners
  - Manufactured from A-CLASS® highly crosslinked ultra high molecular weight polyethylene)
  - Available in Standard, Lipped or Face-changing Lateralized configurations
  - Inner Diameter sizes 22mm to 44mm
- Bone Screws
  - Manufactured from titanium alloy
  - 6.5mm diameter
  - Available in lengths 15mm to 80mm in 5mm increments

MicroPort Orthopedics Inc.

C. Substantial Equivalence Information

The indications for use of the PROCOTYL® PRIME Acetabular Cup System are identical to those for the predicate devices. The identical highly crosslinked UHMWPE material was characterized for the predicate liner in K052026. The design features and materials are substantially equivalent to those of the predicate devices. The fundamental scientific technology of the subject devices has not changed relative to the predicate devices. The safety and effectiveness of the subject devices are adequately supported by the substantial equivalence information, materials information, and analysis data provide within this Premarket Notification.

D. Nonclinical Testing

The lock detail of the subject PROCOTYL® PRIME Acetabular Cup System was evaluated by testing Push-out, Lever-out and Torque-out of the Liner per ASTM 1820.

The subject System underwent deformation and frictional torque testing to evaluate the properties under pinch-loading conditions.

The subject System completed long term axial cyclic loading to evaluate fatigue resistance properties.

The subject System underwent wear testing to determine the wear rate and a wear particle analysis was performed on the wear debris.

Additionally, a range of motion study was completed for the PROCOTYL® PRIME Acetabular Cup System.

Finally, per ASTM F543, the properties of the cancellous bone screws were examined.

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. Furthermore, that the materials and processing methods of the subject device are identical to predicates K002149, K082924, K052026, and K864626. No subject implants use colorants. Therefore, biocompatibility testing was not completed on the subject devices.

The Limulus Amebocyte Lysate (LAL) test was used to determine the subject devices meets the specified pyrogen limit specification of ≤ 20 EU/device.

For all associated instruments that were not previously cleared, Master File references were provided for raw material biocompatibility and manufacturing process effects on biocompatibility were evaluated.

G. Component and Accessory Compatibility

Tables 1 and 2 show the compatibility of the subject device with previously cleared MicroPort Orthopedics products.

Table 1: PROCOTYL® PRIME Acetabular Cup System Compatibility

510(k)	Intended Combinations
Subject Liners Compatibility with Modular Femoral Heads (up to 44mm)	
K893685	Ceramic-Polyethylene with ID 28-36mm**
K920593	Ceramic-Polyethylene, OD 28mm
K925512	Ceramic-Polyethylene, OD 28mm
K932222	Metal-Polyethylene, OD 28mm XXL
K002149	Metal-Polyethylene with ID 22-32mm
K021349*	Metal-Polyethylene with ID 38-56mm
K004043*	Metal-Polyethylene with ID 28-36mm
K051348*	Metal-Polyethylene with ID 38-56mm
K072656	Ceramic-Polyethylene with ID 38-46mm with neck sleeves
K130376	Ceramic-Polyethylene with ID 32-40mm
K140043	Ceramic-Polyethylene with ID 28mm
Subject Shell Compatibility with Bone Screws	
K864626	Cancellous Bone Screws
Subject Screws Compatibility with Acetabular Shells	
K002149	LINEAGE® System Shells
K061547	DYNASTY® PC Shells
K070785	DYNASTY® PC Shells
K082924	DYNASTY® BIOFOAM® Shells
K122382	DYNASTY® BIOFOAM® Shells
K142119	PROCOTYL® L/O Shells

* Metal femoral heads in K021349, K004043 and K051348 were originally cleared for use with metal-metal bearings, and later cleared for compatibility with DYNASTY® A-CLASS® polyethylene liners in K070785.

**36mm Forte Ceramic heads were originally cleared for use in PMA P030027, and later cleared for compatibility with Procotyl L / O Acetabular System in K142119.

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

The PROCOTYL® PRIME Acetabular Cup System instrumentation includes reamers, trial shells, trial liners, impactors and impactor handles, extraction instruments, and screw instruments. The PROCOTYL® PRIME Acetabular Cup System may be used with alternative surgical approaches submitted in K122382; related instrumentation is included in the subject biocompatibility and surgical technique information.

H. Sterilization Residuals

Summary residuals results related to Ethylene Oxide sterilization were provided previously in K140043. Worst-case device was selected based on product, density, size, and worst case for Ethylene Oxide sterilization. Selected devices were LINEAGE® Acetabular Poly Liner (K002149), LINEAGE® Ceramic Head (K893685).

I. Conclusions

The substantial equivalence of the PROCOTYL® PRIME Acetabular Cup System is adequately supported by the substantial equivalence information, materials information, and nonclinical testing data provided within this premarket notification.