August 13, 2019

MicroPort Orthopedics, Inc.
Ms. Sarah Stroupe
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

Re: K171181
Trade/Device Name: PROCOTYL® PRIME E-CLASS™ XLPE Liner
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, OQI, LPH, OQG
Dated: July 28, 2017
Received: August 1, 2017

Dear Ms. Stroupe:

This letter corrects our substantially equivalent letter of August 28, 2017.

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,

Vesa Vuniqi -S Date: 2019.08.13 15:02:35 -04'00'

Vesa Vuniqi
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171181

Device Name
PROCOTYL® PRIME E-CLASS™ XLPE Liner

Indications for Use *(Describe)*

PROCOTYL® PRIME hip system is 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, ankyloses, protrusion 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.

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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 Substantial Equivalence for the PROCOTYL® PRIME E-CLASS™ XLPE Liner.

Submitted by:	MicroPort Orthopedics Inc. 5677 Airline Rd, Arlington TN, 38002 Phone: 866-872-0211 Fax: 855-446-2247
Date:	August 25, 2017
Contact Person:	Sarah Evonne Stroupe *Regulatory Affairs Specialist II*
Proprietary Name:	PROCOTYL® PRIME E-CLASS™ XLPE Liner
Common Name:	Acetabular Liner
Classification Name and Reference:	21 CFR 888.3353 LZO/OQI Hip joint metal/ceramic/polymer semi constrained cemented or nonporous, uncemented prosthesis Class II 21 CFR 888.3358 LPH/OQG Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis Class II
Subject Product Code and Panel Code:	Orthopedics/87/LZO/LPH/OQG/OQI
Primary Predicate Device:	PROCOTYL® PRIME Acetabular Cup System (K170444)
Additional Predicate Devices:	LINEAGE® Acetabular System (K002149 and K052026) DYNASTY® Acetabular System (K082924, K061547, and K070785)
Reference Device:	StelKast's EXp Acetabular Liner (K094035, Models SC3342 Non-Hooded 28mm, SC3343 Hooded 28mm)

DEVICE INFORMATION

A. Intended Use

The PROCOTYL® PRIME E-CLASS™ XLPE Liner is intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients. This device is indicated for the following conditions:

1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankyloses, protrusion 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.

B. Device Description

The PROCOTYL® PRIME E-CLASS™ XLPE Liner is an additional liner option for MicroPort Orthopedics' PROCOTYL® PRIME Acetabular Cup System (K170444). The design features are summarized below:

- Manufactured from E-CLASS™ vitamin E blended highly crosslinked ultra high molecular weight polyethylene (VEXLPE) conforming to ASTM F2695-12
- Available in Standard, Lipped, or Face-Changing Lateralized Configurations
- Inner Diameter sizes 22mm to 44mm

C. Substantial Equivalence Information

The design features and materials of the subject devices are substantially equivalent to those of the predicate and reference devices. The indications for use are identical to the predicate and reference devices. The fundamental scientific technology of the modified devices has not changed relative to the predicate and reference devices. The safety and effectiveness of the subject devices are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

D. Nonclinical Testing

The following nonclinical testing was performed to evaluate the E-CLASS™ material and design of the finished product.

The subject Acetabular Liner underwent material properties testing to compare its properties to those of currently marketed UHMWPE.

The subject Acetabular Liner was evaluated for bacterial endotoxins and found to be less than the USP endotoxin limit of 20 EU/device.

The subject Acetabular Liner underwent pre- and post-fatigue push-out, lever-out, and torque-out testing to evaluate its lock detail.

The subject Acetabular Liner underwent frictional torque testing to evaluate properties under pinch-loading conditions.

The subject Acetabular Liner complete long term axial cyclic loading to evaluate the subject Acetabular Liner's mechanical integrity and fatigue resistance properties.

The subject Acetabular Liner underwent impingement testing to evaluate its mechanical integrity during lip impingement in a fatigue loading profile.

The subject Acetabular Liner underwent wear testing to determine the wear rate. A wear particle analysis was performed on the wear debris.

Additionally, a range of motion study was performed for the PROCOTYL® PRIME Acetabular Cup System, originally submitted as part of K170444.

E. Clinical Testing

Clinical data was not provided for the subject devices.

F. Biocompatibility

Both bench and animal studies were performed to evaluate the biocompatibility of the E-CLASS™ material.

The E-CLASS™ material underwent an extractables study to determine it's the irritant potential of the material and to compare this potential to currently marketed Vitamin E UHMWPE.

The E-CLASS™ material underwent cytotoxicity testing, performed using cell monolayers, to determine the irritant potential of the material.

The E-CLASS™ material underwent irritation and sensitization studies, performed on animal specimens, to determine the irritant and allergenic potential of the material.

No biocompatibility testing was performed for the associated instrumentation, as all associated instruments have been previously cleared.

G. Component and Accessory Compatibility

The PROCOTYL® PRIME E-CLASS™ XLPE Liner may be used with PROCOTYL® PRIME Acetabular Cup System Acetabular Shells and Instrumentation (K170444).

The PROCOTYL® PRIME E-CLASS™ XLPE Liners may be used with previously cleared MicroPort Femoral Heads.

Table 1 shows the compatibility of the subject Acetabular Liner with previously cleared MicroPort Orthopedics products.

Table 1: Subject Acetabular Liners Compatibility

510(k)	Intended Combinations
with 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
with Acetabular Shells	
K170444	Quad and Solid Acetabular Shells
with Instrumentation	
K170444	Acetabular Liner Trials

*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.

H. Conclusion

The indications for use and fundamental scientific technology of the PROCOTYL® PRIME E-CLASS™ XLPE Liner are similar to the predicate and reference devices. The materials of the subject device are considered to be substantially equivalent to the predicate and reference devices. The design features, materials information, predicate and subject testing, and analysis provided in the Master File support the substantial equivalence of the PROCOTYL® PRIME E-CLASS™ XLPE Liner.