September 14, 2018

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

Re: K181598
Trade/Device Name: 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
Dated: June 15, 2018
Received: June 18, 2018

Dear Sarah Stroupe:

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 and Part 809); 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm](https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm)); 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 [http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm](http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm).

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice ([https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/)) and CDRH Learn ([http://www.fda.gov/Training/CDRHLearn](http://www.fda.gov/Training/CDRHLearn)). 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 ([http://www.fda.gov/DICE](http://www.fda.gov/DICE)) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

[Digitally signed by Vesa Vuniqi -S]

Date: 2018.09.14 18:13:22 -04'00'

For: Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

Device Name
Prime E-CLASS™ XLPE Liner

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.

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."
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 use of the 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 30, 2018

Contact Person: Sarah Evonne Stroupe
Sr. Regulatory Affairs Specialist

Proprietary Name: 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

Predicate Devices:
PROCOTYL® PRIME E-CLASS™ XLPE Liner (K171181)
Prime Acetabular Cup System XLPE Liner (K180798)
Reference Devices:

- PROCOTYL® PRIME Acetabular Cup System (K170444)
- LINEAGE® Acetabular System (K002149 and K052026)
- DYNASTY® Acetabular System (K002149, K061547, K070785, and K082924)

DEVICE INFORMATION

A. Intended Use

The Prime E-CLASS™ XLPE Liner is an acetabular liner 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 Prime E-CLASS™ XLPE Liner is an additional liner option for MicroPort Orthopedics’ Prime Acetabular Cup System (K170444; K180798). The subject Liner is intended to be used with Acetabular Shells and optional Cancellous Bone Screws as part of a total acetabular system.

The Prime E-CLASS™ XLPE Liner is manufactured from E-CLASS™, a vitamin E blended XLPE, conforming to ASTM F2695-12. The subject Liner is available in Standard, Lipped, and Lateralized/Face-changing configurations. The subject Liner has a two-part locking detail featuring 12 anti-rotational tabs and a lock flange, which is intended to mate with the 12 anti-rotational pockets and lock groove of the compatible Prime Acetabular Shells (K170444; K180798).
C. Substantial Equivalence Information
The subject Liner’s intended use, size range, articulating surface, and available configurations are identical to the predicates K171181 and K180798. The subject Liner’s material (E-CLASS™) is identical to the predicate K171181. The subject Liner’s geometry is identical to the predicate K180798.

The fundamental scientific technology of the subject Liner has not changed relative to the predicates.

Based on these similarities, the Prime E-CLASS™ XLPE Liner is believed to be substantially equivalent to the predicate devices.

D. Nonclinical Testing
Nonclinical testing performed on the to establish the basis for substantial equivalence of the Prime E-CLASS™ XLPE Liner included bacterial endotoxin testing and mechanical testing of the lock detail.

- Bacterial endotoxin testing was performed per ANSI/AAMI ST72:2011; endotoxins were found to be less than the USP endotoxin limit of 20 EU/device;
- Mechanical testing of the lock detail was performed through Pre- and Post- Fatigue Push-out Lever-out and Torque-out of the subject Liner from a compatible Shell (K170444; K180798) per ASTM F1820, ASTM STP1301, and testing found in literature. Axial long-term fatigue per FDA Draft Guidance Documents “Guidance Document for Testing Acetabular Cup Prostheses” and “Guidance Document for Testing Non-Articulating ‘Mechanically-Locked’ Modular Implant Components”, both issued May 1, 1995, was also evaluated as part of this study.

Due to the subject Liner’s identical material and articulating surface, the following testing performed for K171181 is considered applicable:

- Wear particle analysis per ASTM F1877-05;
• Long-term fatigue per FDA Draft Guidance Documents “Guidance Document for Testing Acetabular Cup Prostheses” and “Guidance Document for Testing Non-Articulating ‘Mechanically-Locked’ Modular Implant Components”, both issued May 1, 1995; and,
• Deformation and frictional torque per ISO 7206-12.

Due to the subject Liner’s identical articulating surface and configurations, the following testing performed for K170444 is considered applicable:
• Range of motion per ISO 21535

E. Clinical Testing
Clinical data was not necessary to determine substantial equivalence between the Prime E-CLASS™ XLPE Liner and the predicate devices.

F. Biocompatibility
The Prime E-CLASS™ XLPE Liner is manufactured from the identical E-CLASS™ material characterized for the predicate K171181. Intended patient contact also remains identical. Therefore, biocompatibility testing performed for K171181 remains applicable to the subject device. Biocompatibility bench and animal studies used to characterize the E-CLASS™ material included extractables, cytotoxicity, irritation, and sensitization studies.

The Prime E-CLASS™ XLPE Liner is implanted using the same instrumentation cleared within K170444; no new biocompatibility assessment is required.

G. Component and Accessory Compatibility
The Prime E-CLASS™ XLPE Liner is compatible with Prime Acetabular Cup System Shells (K170444; K180798) and Instrumentation (K170444). The Prime E-CLASS™ XLPE Liner is also compatible with previously cleared MicroPort Femoral Heads.

Compatibility of the subject Liner with previously cleared MicroPort Orthopedics products is listed in Table 1.
Table 1: Prime E-CLASS™ XLPE Liner Compatibility

<table>
<thead>
<tr>
<th>510(k)</th>
<th>Intended Combinations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>with Femoral Heads (up to 44mm)</td>
</tr>
<tr>
<td>K893685</td>
<td>Ceramic-Polyethylene with ID 28-36mm**</td>
</tr>
<tr>
<td>K920593</td>
<td>Ceramic-Polyethylene, OD 28mm</td>
</tr>
<tr>
<td>K925512</td>
<td>Ceramic-Polyethylene, OD 28mm</td>
</tr>
<tr>
<td>K932222</td>
<td>Metal-Polyethylene, OD 28mm XXL</td>
</tr>
<tr>
<td>K002149</td>
<td>Ceramic-Polyethylene with ID 22-32mm</td>
</tr>
<tr>
<td>K021349*</td>
<td>Metal-Polyethylene with ID 38-56mm</td>
</tr>
<tr>
<td>K004043*</td>
<td>Metal-Polyethylene with ID 28-36mm</td>
</tr>
<tr>
<td>K051348*</td>
<td>Metal-Polyethylene with ID 38-56mm</td>
</tr>
<tr>
<td>K072656</td>
<td>Ceramic-Polyethylene with ID 38-46mm with neck sleeves</td>
</tr>
<tr>
<td>K130376</td>
<td>Ceramic-Polyethylene with ID 32-40mm</td>
</tr>
<tr>
<td>K140043</td>
<td>Ceramic-Polyethylene with ID 28mm</td>
</tr>
<tr>
<td></td>
<td>with Acetabular Shells</td>
</tr>
<tr>
<td>K170444</td>
<td>Quad and Solid Acetabular Shells</td>
</tr>
<tr>
<td>K180798</td>
<td>Quad and Solid Acetabular Shells</td>
</tr>
<tr>
<td></td>
<td>with Instrumentation</td>
</tr>
<tr>
<td>K170444</td>
<td>Acetabular Liner Trials</td>
</tr>
</tbody>
</table>

*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. Sterilization Residuals
Ethylene Oxide sterilization of the subject Liner was evaluated per AAMI TIR 28:2009 Annex A. The evaluation determined that sterilization residuals are within the limits determined by the worst case, which was presented in K140043 as established by product density, product size, and worst case sterilization conditions.

I. Conclusion
The indications for use and fundamental scientific technology of the Prime E-CLASS™ XLPE Liner are identical to the predicate and reference devices. The subject Liner’s geometry is identical to the predicate K180798. The subject Liner’s material is identical to the predicate K171181. Additionally, the Prime E-CLASS™ XLPE Liner’s compatibility with other components is identical to the predicate liners cleared within K171181 and K180798. The predicate and subject testing and analyses support the substantial equivalence of the Prime E-CLASS™ XLPE Liner’s performance.