



Food and Drug Administration
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MicroPort Orthopedics, Inc.
Mr. Byron Ledbetter
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

February 27, 2015

Re: K142119

Trade/Device Name: PROCOTYL[®] L-O Acetabular 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

Dated: January 20, 2015

Received: January 22, 2015

Dear Mr. Ledbetter:

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" (21CFR 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 yours,

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

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K142119

Device Name

PROCOTYL® L-O Acetabular System

Indications for Use (Describe)

The PROCOTYL® L-O Acetabular 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

The PROCOTYL® L-O Acetabular System utilizes single use components, intended for use in conjunction with associated ceramic femoral heads as part of uncemented total hip 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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MicroPort Orthopedics Inc.

PROCOTYL® L-O Acetabular System
 Traditional 510(k)
 510(k) Summary

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 Safety and Effectiveness for the use of the PROCOTYL® L-O Acetabular System.

Submitted by:	MicroPort Orthopedics Inc. 5677 Airline Rd Arlington, TN 38002 Phone: (866) 872-0211 Fax: (855) 446-2247
Date:	February 18, 2015
Contact Person:	Byron Ledbetter <i>Regulatory Affairs Specialist II</i>
Proprietary Name of Modified Device:	PROCOTYL® L-O Acetabular System
Common Name:	acetabular shell, acetabular liner and femoral head
Classification Name and Reference:	888.3358 LPH Hip joint metal/polymer/metal semi- Constrained porous-coated uncemented prosthesis Class II 888.3353 LZ0 Hip joint metal/ceramic/polymer semi constrained cemented or nonporous, uncemented prosthesis Class II
Subject Product Code and Panel Code:	Orthopedics/87/LPH/LZO
Predicate Devices:	LINEAGE™ Acetabular System (K002149 shells; K052026 liners) DYNASTY® Acetabular System (K130376 28mm heads; K140043 32-36mm heads)

Device Description

The PROCOTYL® L and O acetabular cup designs are based off the LINEAGE™ Acetabular System (K002149) which was designed from the TRANSCEND® product line. The subject PROCOTYL® acetabular system of this submission includes the PROCOTYL® L Acetabular Cup, the PROCOTYL® O Acetabular Cup, RIM-LOCK “A-CLASS®” Acetabular Poly Liner and BIOLOX® delta Ceramic Femoral Head.

Intended Use

The PROCOTYL® L-O Acetabular 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

The PROCOTYL® L-O Acetabular System utilizes single use components, intended for use in conjunction with associated ceramic femoral heads as part of uncemented total hip arthroplasty.

Technological Characteristics of the Device

The indications for use of the PROCOTYL® L-O Acetabular System are identical to those for the predicate devices for the head (K130376 and K140043) and shells/liners (K002149). The subject devices are made from an identical Titanium Alloy, Ti6Al4V, wrought or forged (ASTM F136 or ASTM F620 respectively) and possess an identical titanium plasma spray coating (ASTM F1580) or beaded coating (ASTM F1580/F67) as the predicate device.

Nonclinical Testing

The PROCOTYL® L-O Acetabular System ceramic heads were evaluated for static compression to failure and were deemed acceptable per ISO 7206-10. Additionally, the PROCOTYL® L-O Acetabular System was evaluated for range of motion and was deemed acceptable per ISO 21535.

Clinical Testing

Clinical data was not provided for the subject devices.

Conclusions

The indications for use and fundamental scientific technology of the PROCOTYL® L-O Acetabular System are identical to those of the predicate devices. The design features and materials of the subject devices are substantially equivalent to those of the predicate devices. The safety and effectiveness of the PROCOTYL® L-O Acetabular System are adequately supported by the substantial equivalence information, materials information, and nonclinical testing data provided within this premarket notification.