DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 20, 2015

MicroPort Orthopedics, Incorporated
Mr. Byron Ledbetter
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

Re: K150133
Trade/Device Name: PROFEMUR® Preserve Sizes 1-3 Hip Stems
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, JDI, LPH, MBL
Dated: December 23, 2014
Received: January 21, 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,

Lori A. Wiggins -S

for
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)*

K150133 (pg 1/1)

Device Name
PROFEMUR® Preserve Sizes 1-3 Hip Stems

Indications for Use *(Describe)*

The PROFEMUR® Preserve Sizes 1-3 Hip Stems 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

The PROFEMUR® Preserve Sizes 1-3 Hip Stems are single use components, intended for use in conjunction with associated ceramic or metal 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)*

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.

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"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 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the PROFEMUR® Renaissance® Classic Long Neck Hip Stems.

Submitted by:	MicroPort Orthopedics Inc. 5677 Airline Rd Arlington, TN 38002 Phone: (866) 872-0211 Fax: (855) 446-2247
Date:	December 23, 2014
Contact Person:	Byron Ledbetter *Regulatory Affairs Specialist II*
Proprietary Name of Modified Device:	PROFEMUR® Preserve Sizes 1-3 Hip Stems
Common Name:	Femoral Hip Stem
Classification Name and Reference:	888.3353 LZO Hip joint metal/ceramic/polymer semi constrained cemented or nonporous, uncemented prosthesis Class II

888.3350 JDI
Hip joint metal/polymer semi-constrained cemented prosthesis
Class II

888.3358 LPH
Hip joint metal/polymer/metal semi-Constrained porous-coated uncemented prosthesis
Class II

888.3358 MBL
Hip joint metal/polymer/metal semi-Constrained poruous-coated uncemented prosthesis
Class II

Subject Product Code and Panel Code: Orthopedics/87/LZO/JDI/LPH/MBL

Predicate Devices: PROFEMUR® Preserve Hip Stems, K112080

Device Description

The purpose of this submission is to provide additional sizing options for the predicate PROFEMUR® Preserve Hip Stems (K112080) by adding a line extension. The PROFEMUR® Preserve Sizes 1-3 Hip Stems are modular stems manufactured from a forged titanium alloy (ASTM F620) and designed for use in uncemented total hip arthroplasty. The PROFEMUR® Preserve Sizes 1-3 Hip Stems are available in three configurations and are coated with titanium plasma spray conforming to ASTM F1580.

Intended Use

The PROFEMUR® Preserve Sizes 1-3 Hip Stems 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, 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 PROFEMUR® Preserve Sizes 1-3 Hip Stems are single use components, intended for use in conjunction with associated ceramic or metal femoral heads as part of uncemented total hip arthroplasty.

Technological Characteristics of the Device
The indications for use of the PROFEMUR® Preserve Sizes 1-3 Hip Stems are identical to those for the predicate device (K112080). The subject devices are made from an identical titanium alloy (ASTM F620) and possess an identical titanium plasma spray coating (ASTM 1580) as the predicate device. The PROFEMUR® Preserve Sizes 1-3 Hip Stems are designed to provide geometry which is similar to those available with the predicate device.

Nonclinical Testing
The PROFEMUR® Preserve Sizes 1-3 Hip Stems were evaluated by proximal and distal fatigue tests in accordance with ISO 7206-4 and ASTM F2068. The devices satisfied the acceptance criteria of each standard.

Range of motion was evaluated and satisfied the acceptance criteria of ISO 21535.

Clinical Testing
Clinical data was not provided for the subject devices.

Conclusions
The indications for use and fundamental scientific technology of the PROFEMUR® Preserve Sizes 1-3 Hip Stems are identical to those of the predicate device. The design features and materials of the subject devices are substantially equivalent to those of the predicate devices. The safety and effectiveness of the PROFEMUR® Preserve Sizes 1-3 Hip Stems is adequately supported by the substantial equivalence information, materials information, and nonclinical testing data provided within this premarket notification.