MicroPort Orthopedics Inc.
Sneh Pingle
Project Manager, Regulatory Affairs
5677 Airline Road
Memphis, Tennessee 38002

October 7, 2019

Re: K191632
Trade/Device Name: PROFEMUR TL2 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
Dated: September 9, 2019
Received: September 10, 2019

Dear Sneh Pingle:

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,

FOR Vesa Vuniqi
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191632

Device Name

PROFEMUR® TL2 Stem System

Indications for Use *(Describe)*

PROFEMUR® TL2 stems are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

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

Titanium plasma spray coatings applied to implant surfaces are intended 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.

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510(k) Summary

Submitted By:	MicroPort Orthopedics Inc. 5677 Airline Road Arlington, TN 38002 Telephone Number: (901) 290-5175
Date of Submission:	June 18, 2019
Contact Person:	Sneh Pingle Project Manager, Regulatory Affairs Telephone number: (901) 867-4656 Email: sneh.pingle@ortho.microport.com
Name of Device:	PROFEMUR® TL2 Stem
Common Name:	Femoral Hip Stem
Device Classification Name And Reference:	21 CFR 888.3353- Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Device Class:	Class II
Panel Code:	Orthopedics/87
Product Code:	LZO
Predicate Device:	PROFEMUR® TL CLASSIC HIP STEM (K123688, SE 02/08/2013) This predicate has not been subject to a design-related recall.

Device Description:

The PROFEMUR® TL2 stems are monolithic wedge taper style stems manufactured from forged titanium alloy conforming to ASTM F620. The proximal portion (top third) of the TL2 stem possesses a titanium plasma spray coating, manufactured from pure titanium powder conforming to ASTM F1580. The stems will have a glass-beaded finish everywhere except for the trunnion and plasma spray coating region. The PROFEMUR® TL2 stems also have a vertical groove along most of the distal length of the stem to assist in rotational stability in the canal. The PROFEMUR® TL2 stems are designed for use in uncemented total hip arthroplasty. The PROFEMUR TL2 Stem is offered in 3 different neck variants, Standard (STD), High Offset (HO), and Ultra High Offset (UHO). The PROFEMUR TL2 Stems will be offered in sizes 0-12 for Standard (STD) and High Offset (HO), and 1-5, 11 & 12 in Ultra High Offset (UHO) with M/L Width ranging from 27-40mm and A/P width ranging from 13-17mm. All stem variants; standard, high offset, and ultra high offset were designed to accommodate a wide range of patient anatomy and to provide an optimized fit to adequately restore the biomechanics of the respective hip (including restoration of the natural leg length and head center offset). The PROFEMUR® TL2 stems are single use devices which will be provided sterile via Gamma Irradiation.

Indications for Use:

PROFEMUR® TL2 stems are 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, 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

Titanium plasma spray coatings applied to implant surfaces are intended for uncemented arthroplasty.

Comparison of Technological Characteristics with the Predicate devices:

Device comparison described in this premarket notification demonstrate that the subject PROFEMUR® TL2 stems are substantially equivalent to the identified predicate PROFEMUR® TL Classic Hip Stems cleared by the FDA for commercial distribution in the United States. The subject devices were shown to be substantially equivalent and have equivalent technological characteristics to their predicate devices in areas including design, intended use, material composition, operational principles and function.

Discussion of the Non-clinical Testing/Performance Data:

Mechanical Testing:

MicroPort has evaluated the subject PROFEMUR® TL2 Stems to demonstrate substantial equivalence to the identified predicate PROFEMUR® TL Classic Hip Stems. Design verification testing for the subject implants was completed in accordance with

- ASTM-F2996 (2013): Standard Practice for Fine Element Analysis (FEA) of Non-Modular Metallic Orthopedic Hip Femoral Stems
- ISO 7206-4 (2010): Implants for surgery – Partial and total – hip joint prostheses – part 4 Determination of endurance properties and performance of stemmed femoral components.
- ISO 7206-6 (2013): Implants for surgery -- Partial and total hip joint prostheses - Part 6: Endurance properties testing and performance requirements of neck region of stemmed femoral components.
- ASTM F2068 (2015): Standard Specification for Femoral Prostheses—Metallic Implants.
- ISO 21535 (2007): Non-active surgical implants -- Joint replacement implants -- Specific requirements for hip-joint replacement implants.

The testing performed for the subject PROFEMUR® TL2 Stems were:

A. Finite Element Analysis, (FEA),
B. Proximal Fatigue Evaluation,
C. Distal Fatigue Evaluation,
D. Range of Motion (ROM),

The mechanical testing verifies that the subject PROFEMUR® TL2 Stems are substantially equivalent to the predicate PROFEMUR® TL Classic Hip Stems currently on the market and has met all mechanical testing requirements based on the worst case construct testing.

Non-Pyrogenicity Endotoxin Testing:

The bacterial endotoxin test, also known as Limulus amebocyte lysate (LAL) test, was performed utilizing worst case implants to verify that the subject implants meet the 20 endotoxin units (EU)/device pyrogen limit specification. The subject PROFEMUR® TL2 Stems were adopted into the current worst case Hip Stem and Neck Endotoxin Family based on the product process operations. Testing was successfully performed and it was confirmed that the worst case implants meet the 20 EU/device testing limit for general medical devices that are implanted as outlined in ANSI/AAMI ST72, Bacterial endotoxins – Test methods, routine monitoring, and

alternatives to batch testing and USP <161>, Medical Devices – Bacterial Endotoxin and Pyrogen Tests.

Conclusion:

Based on the design features, the use of established well-known materials, feature comparisons, indications for use, principle of operations and results of the mechanical testing, the subject PROFEMUR® TL2 Stem have shown to be substantially equivalent to the legally marketed predicate devices cited in this premarket notification.