April 25, 2020

MicroPort Orthopedics Inc.
Allen Mamaril
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

Re: K200007
Trade/Device Name: PROFEMUR GLADIATOR Thin HA Classic Hip Stem with Collar
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, LPH
Dated: December 30, 2019
Received: January 2, 2020

Dear Allen Mamaril:

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, MS
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)*

K200007

Device Name
PROFEMUR® GLADIATOR® Thin HA Classic Stems w/ Collar

Indications for Use *(Describe)*

PROFEMUR® GLADIATOR® Thin HA Classic Stems w/ Collar 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

Hydroxyapatite 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.

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510(k) Summary

In accordance with 21 CFR 807.92, this information serves as a summary of information upon which MicroPort Orthopedics claims substantial equivalence for the subject PROFEMUR® GLADIATOR® Thin HA Classic Stem with Collar.

Submitted by:	MicroPort Orthopedics Inc. 5677 Airline Road, Arlington, TN 38002 USA Phone: (901) 290-5175
Date:	December 20, 2019
Contact Person:	Allen Mamaril Regulatory Affairs Specialist II Phone: (901) 867-4551
Proprietary Name:	PROFEMUR® GLADIATOR® Thin HA Classic Stem with Collar
Common Name:	Femoral Hip Stem
Classification Name and Reference:	21 CFR 888.3353 – Hip joint metal/ceramic/ polymer semi-constrained cemented or nonporous uncemented prosthesis 21 CFR 888.3358 – Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Device Class:	Class II
Panel Code:	Orthopedic/87
Product Code:	LZO, LPH
Predicate Device:	K112150 PROFEMUR® GLADIATOR® HA Hip Stem
Reference Device:	K110399 PROFEMUR® GLADIATOR® Plasma Classic Hip Stem K191632 PROFEMUR® TL2 Stems K190123 MicroPort CoCr Femoral Heads

A. Device Description

The PROFEMUR® GLADIATOR® Thin Hydroxyapatite-coated (HA) Classic Stems with Collar present a monolithic, tapered-wedge design and a reduced distal stem tip. The 'Thin' description is a relative word MicroPort uses as an internal descriptor to clearly identify the difference in product between the currently cleared US-offered HA coating thickness (65µm) and the coating thickness offered in outside US (OUS) markets. The subject stems are coated with a 65µm HA coating (ASTM 1185), and the uncoated medial collar, proximal shoulder and neck regions of the stem possess a glass-beaded finish (Ra=0.8µm). The subject stems possess a proximal medial collar designed to assist in discouraging subsidence and maximizing rotational stability. The proximal anterior, posterior, and medial surfaces possess grooves perpendicular to the stem's longitudinal axis and parallel with each other. The proximal grooves are designed to provide a maximized bone-stem contact surface for bone apposition and assist in discouraging stem subsidence. The distal anterior and posterior surfaces of the subject stem possess vertical grooves parallel to the stem's longitudinal axis. The distal grooves are designed to assist the stem in resisting against rotational loads. The subject classic stems possess an oval impaction feature on the proximal shoulder for stem insertion into the femoral canal. The PROFEMUR® GLADIATOR® Thin HA Classic Stems w/ Collar are designed for use in total hip arthroplasty.

The PROFEMUR® GLADIATOR® Thin HA Classic Stems w/ Collar are manufactured from forged Ti6Al4V alloy (ASTM F620) and come in 10 sizes, with the stem length ranging from 125mm to 175mm. The subject stems features two different neck options: standard (with a CCD neck angle of 135°) and extended/Varus 8º (with a CCD angle of 127º). The PROFEMUR® GLADIATOR® Thin HA Classic Stems w/ Collar 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).

B. Intended Use

PROFEMUR® GLADIATOR® Thin HA Classic Stems w/ Collar 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

Hydroxyapatite coatings applied to implant surfaces are intended for uncemented arthroplasty.

C. Substantial Equivalence Information

The design features and materials of the PROFEMUR® GLADIATOR® Thin HA Classic Stems w/ Collar are substantially equivalent to those of the predicate cleared under K112150. The indications of the subject devices are identical to the predicate. The fundamental scientific technology of the subject device has not changed relative to the predicate device. The safety and effectiveness of the subject devices are adequately supported by the substantial equivalence information, materials information, and analysis of data provided within this Premarket Notification.

D. Nonclinical Testing

The subject PROFEMUR® GLADIATOR® Thin HA Classic Stems w/ Collar were evaluated to demonstrate substantial equivalence to the identified predicate PROFEMUR® GLADIATOR® HA Hip Stem and reference PROFEMUR® GLADIATOR® Plasma Classic Hip Stem. Design verification testing for the subject devices was completed in accordance with:

- 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;
- EN ISO 21535 (2009) Non-active surgical implants – Joint replacement implants – Specific requirements for hip-joint replacement implants.
- ASTM F2052-15 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in Magnetic Resonance Environment
- ASTM F2119-07 Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
- ASTM F2182-11a Standard Test Method for Measurement of Radio Frequency Induced Heating on or Near Passive Implants During Magnetic Resonance Imaging
- ASTM F2503-13 Standard Practice for marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

The testing and analyses performed for the subject PROFEMUR® GLADIATOR® Thin HA Classic Stems w/ Collar were:

- Distal Fatigue Testing
- Proximal Fatigue Testing
- Range of Motion Analysis
- Magnetic Resonance Imaging Safety Analysis
- Coating Characterization of the Hydroxyapatite Coating

The mechanical testing and coating characterization verifies the subject PROFEMUR® GLADIATOR® Thin HA Classic Stems w/ Collar are substantially equivalent to the cleared predicate PROFEMUR® GLADIATOR® HA Hip Stem and cleared reference PROFEMUR® GLADIATOR® Plasma Classic Hip Stem currently on the market and has met all mechanical testing requirements based on the worst-case construct testing.

E. 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® GLADIATOR® Thin HA Classic Stems w/ Collar 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.

F. Conclusion

Based on the design features, the use of established well-known materials, feature comparisons, indications for use, and results of the mechanical testing, the subject PROFEMUR® GLADIATOR® Thin HA Classic Stems w/ Collar have shown to be substantially equivalent to the legally marketed devices cited in this summary.