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

Re: K201519
Trade/Device Name: PROFEMUR® GLADIATOR® Cemented Classic Stem
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JDI, KWL, KWY, LZO
Dated: November 12, 2020
Received: November 13, 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,

for

Vesa Vuniqi
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)*

K201519

Device Name
PROFEMUR® GLADIATOR® Cemented Classic Stems

Indications for Use *(Describe)*

PROFEMUR® GLADIATOR® Cemented Classic 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

PROFEMUR® GLADIATOR® Cemented Classic Stems are single use implants intended for cemented 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

Submitted By:	MicroPort Orthopedics Inc. 5677 Airline Road Arlington, TN 38002 USA Telephone Number: (901) 290-5717
Date:	December 10, 2020
Contact Person:	Allen Mamaril Regulatory Affairs Specialist II Telephone number: (901) 867-4551 Email: Allen.Mamaril@ortho.microport.com
Name of Device:	PROFEMUR® GLADIATOR® Cemented Classic Stem
Common Name:	Femoral Hip Stem
Device Classification Name	21 CFR 888.3350 - Hip joint metal/polymer semi-constrained cemented prosthesis; 21 CFR 888.3360 - Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis; 21 CFR 888.3390 - Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis; 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 Codes:	JDI, KWL, KWY, LZO
Predicate Device:	PROFEMUR® GLADIATOR® Cemented Stem (K111910, SE 10/14/2011)
Reference Device:	PROFEMUR® Cobalt Chrome Modular Necks (K091423, SE 08/25/2009; K100866, SE 04/28/2010) PROFEMUR® GLADIATOR® Thin HA Classic Stem w/ Collar (K200007, SE 04/25/2020)

Device Description:

The PROFEMUR® GLADIATOR® Cemented Classic Stems present a tapered-wedge design and a reduced distal stem tip, identical to the legally marketed modular PROFEMUR® GLADIATOR® Cemented Stem (K111910, SE 10/14/2011) with PROFEMUR® Cobalt Chrome Modular Necks (K091423, SE 08/25/2009; K100866, SE 04/28/2010).

The subject stems are intended to be cemented and have a glass-beaded body, medial collar, proximal shoulder and neck region with a surface roughness identical to the legally marketed modular PROFEMUR® GLADIATOR® Cemented Stem (K111910, SE 10/14/2011) with PROFEMUR® Cobalt Chrome Modular Necks (K091423, SE 08/25/2009; K100866, SE 04/28/2010).

The subject stems possess a proximal medial collar designed to assist rotational stability and offer protection against subsidence, identical to the cleared predicate PROFEMUR® GLADIATOR® Cemented Stem (K111910, SE 10/14/2011) with PROFEMUR® Cobalt Chrome Modular Necks (K091423, SE 08/25/2009; K100866, SE 04/28/2010). The trunnion is a MicroPort 12/14 SLT taper, with an as-machined geometry to form a taper lock with a mating femoral head implant. The trunnion is identical to the MicroPort femoral stem tapers of the predicate and reference devices.

The subject stems possess an oval impaction feature on the proximal shoulder for proper femoral stem insertion into the femoral canal, identical to the cleared reference PROFEMUR® GLADIATOR® Thin HA Classic Stem w/ Collar (K200007, SE 04/25/2020).

Materials

The subject PROFEMUR® GLADIATOR® Cemented Classic Stems are manufactured from forged cobalt chromium alloy (ASTM F799).

Geometry and Dimensions

The PROFEMUR® GLADIATOR® Cemented Classic Stems 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 subject PROFEMUR® GLADIATOR® Cemented Classic Stems are offered in sizes 4, 6, 8, 10, and 12 with the stem length ranging from 125mm to 170mm, identical to the cleared reference PROFEMUR® GLADIATOR® Cemented Stems (K111910, SE 10/14/2011). The subject classic stem possesses two different neck options: standard (with a CCD neck angle of 135°) and extended/Varus 8º (with a CCD angle of 127º).

Intended Use:

PROFEMUR® GLADIATOR® Cemented Classic 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:

The subject device is indicated for 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.

PROFEMUR® GLADIATOR® Cemented Classic Stems are single use implants intended for cemented arthroplasty.

Comparison of Technological Characteristics with the Predicate devices:

Device comparison described in this premarket notification demonstrates that the subject PROFEMUR® GLADIATOR® Cemented Classic Stems are substantially equivalent to the identified predicate, PROFEMUR® GLADIATOR® Cemented Stem (K111910, SE 10/14/2011) with PROFEMUR® Cobalt Chrome Modular Necks (K091423, SE 08/25/2009; K100866, SE 04/28/2010), 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.

Mechanical Testing:

MicroPort has evaluated the subject PROFEMUR® GLADIATOR® Cemented Classic Stems and data demonstrates substantial equivalence to the identified predicate PROFEMUR® GLADIATOR® Cemented Stem (K111910, SE 10/14/2011) with PROFEMUR® Cobalt Chrome Modular Necks (K091423, SE 08/25/2009; K100866, SE 04/28/2010). Applicable design verification testing and engineering analyses for the subject implants were completed in accordance with the following standards:

- ASTM F799-19: Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)
- 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 F2052-6, “Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment”
- ASTM F2119-7 “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 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”
- EN ISO 21535 (2009): Non-active surgical implants – Joint replacement implants – Specific requirements for hip-joint replacement implants

The mechanical testing and engineering analyses performed that are applicable to the subject PROFEMUR® GLADIATOR® Cemented Classic Stems include:

1. Proximal Fatigue Strength Testing and Analysis
2. Distal Fatigue Strength Testing and Analysis
3. Range of Motion (ROM) Testing and Analysis
4. Magnetic Resonance Imaging (MRI) Safety Analysis

The data demonstrates that the subject PROFEMUR® GLADIATOR® Cemented Classic Stems are substantially equivalent to the legally marketed predicate, PROFEMUR® GLADIATOR® Cemented Stem (K111910, SE 10/14/2011) with PROFEMUR® Cobalt Chrome Modular Necks (K091423, SE 08/25/2009; K100866, SE 04/28/2010). Having met all acceptance criteria for mechanical testing performed on worst-case constructs, the subject PROFEMUR® GLADIATOR® Cemented Classic Stems do not introduce new or modified risks for safety and effectiveness compared to the predicate or other reference MicroPort Hip Systems and acetabular components which utilize comparable test methods and acceptance criteria.

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 and engineering analyses, the subject PROFEMUR® GLADIATOR® Cemented Classic Stems have shown to be substantially equivalent to the legally marketed predicate devices cited in this premarket notification.