January 13, 2025

Adler Ortho S.p.A
℅ Mehdi Kazemzadeh-Narbat
Director, Regulatory Affairs
MCRA, LLC
803 7th Street NW, Floor 3
Washington, District of Columbia 20001

Re: K241059
Trade/Device Name: Pantheon Proximal Femur Reconstruction (PFR) 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, JDI, LZO, MBL
Dated: December 9, 2024
Received: December 10, 2024

Dear Mehdi Kazemzadeh-Narbat:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Limin Sun -S

Limin Sun, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241059

Device Name
Pantheon Proximal Femur Reconstruction (PFR) System

Indications for Use *(Describe)*

The Pantheon Proximal Femur Reconstruction (PFR) System is a modular system intended to be used for the reconstruction of the proximal femur in the case of severe proximal femoral bone loss in hip revision surgery (due to infection, fracture, failed THA) or in the case of a bone tumor.

The FIXA Ti-Por cup is intended for cementless use.

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.

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K241059

510(k) Summary

Device Trade Name: Pantheon Proximal Femur Reconstruction (PFR) System

Manufacturer:
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Italy

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Date Prepared: January 13th, 2025

Classifications:
21 CFR 888.3350, Hip joint metal/polymer semi-constrained cemented prosthesis

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.

Class: II

Product Code: LPH, JDI, LZO, MBL

Primary Predicate: Global Modular Replacement System (GMRS®) Proximal Femoral (K023087)

Additional Predicates: Global Modular Replacement System (GMRS®) Proximal Femoral (K040749)
M-SPEC Metal Femoral Heads (K980513)
Biolox Delta Ceramic Femoral Heads (K071535)
Delta TT Acetabular System (K112898)
Pinnacle Altrx Polyethylene Acetabular Liner (K072963)
Zimmer® Segmental System Trabecular Metal Proximal Tibial Component, Trabecular Metal Proximal Femoral Component, and additional Segment with Male/Female Taper components (K110940)

Indications for Use:
The Pantheon Proximal Femur Reconstruction (PFR) System is a modular system intended to be used for the reconstruction of the proximal femur in the case of severe proximal femoral bone loss in hip revision surgery (due to infection, fracture, failed THA) or in the case of a bone tumor.

The FIXA Ti-Por cup is intended for cementless use.

Device Description:
The Pantheon PFR System is manufactured of Ti6Al4V (except for femoral heads which are made of CoCrMo or ceramic and acetabular inserts made of cross-linked UHMWPE) and includes various components that can be combined to replace the hip joint and address major bone defects with various options depending upon the size and location of the defects of each patient. The Pantheon PFR System consists of:

- Pantheon Proximal Bodies made of Ti6Al4V Alloy additively manufactured
    - System compatibility
        - A 12/14 connection taper to connect CoCrMo Alloy or Biolox Delta Ceramic Femoral Heads
        - A female conical taper to connect Pantheon Shaft or intramedullary Pantheon Salvage Stem
        - A through-hole for screw to lock Pantheon Shaft or intramedullary Pantheon Salvage Stem
        - For Pantheon Proximal Body Flat only: lateral threaded holes for Pantheon Salvage Plate Compression Screws
    - Size range
        - Pantheon Proximal Body Flat
            - L50mm (Medium, and long), L70mm (Medium, and long)
        - Pantheon Proximal Body Smooth
            - L50mm (Medium, and long), L70mm (Medium, and long)

- CoCrMo Alloy Femoral Heads Taper 12/14
  - System compatibility
    - Cross-Linked PE Inserts
  - Size range
    - Ø 22m, Ø 28mm, Ø 32mm, Ø 36mm
- Biolox Delta Ceramic Femoral Heads Taper 12/14
  - System compatibility
    - Cross-Linked PE Inserts
  - Size range
    - Ø 22m, Ø 28mm, Ø 32mm, Ø 36mm
- Pantheon Shaft made of Ti6Al4V Alloy
  - System compatibility
    - A female conical taper to connect intramedullary Pantheon Salvage Stems
  - Size range
    - from 35 mm to 200 mm in 15 mm increments
- Pantheon Bridging Collars made of Ti6Al4V Alloy additively manufactured
  - System compatibility
    - A female conical taper to connect intramedullary Pantheon Salvage Stems
  - Size range
    - Ø 26m, Ø 30mm, and, Ø 36mm
- Pantheon Cylindrical Bridging Collars made of Ti6Al4V Alloy additively manufactured
  - System compatibility
    - A female conical taper to connect intramedullary Pantheon Salvage Stems
  - Size range
    - Ø 26 mm, Ø 30 mm, and Ø 36 mm
- Pantheon Salvage Stem (Cemented) made of Ti6Al4V Alloy
  - Size range
    - L115 Ø 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 22 mm
- Pantheon Salvage Stem (Uncemented) made of Ti6Al4V alloy
  - Size range
    - L115 Ø 12, 13, 14, 15, 16, 17, 18, 19, 20, 22, 24 mm
- Pantheon Proximal Body Locking Screw made of Ti6Al4V Alloy
  - Size range
    - L50 mm, L70 mm
- Pantheon Salvage Plate Compression Screws made of Ti6Al4V Alloy
  - Size range
    - Extra-Short, Short, Medium, Long
- Pantheon Salvage Plate with Spikes made of Ti6Al4V Alloy
  - Size range
    - L50 mm, L70 mm
- Fixa Ti-Por Cup – Acetabular Shells made of Ti6Al4V Alloy additively manufactured
  - System compatibility

        - Cross-Linked PE Inserts
        - Lateral Holes Plug
        - Titanium Acetabular Screw
    - Size range
        - Size 48, 50, 52, 54, 56, 58, 60, 62, 64
- Titanium Acetabular Screws made of Ti6Al4V Alloy
    - Size range
        - Diam. 6.5 mm from L15 to L50 mm in 5mm increments
- Acetabular Inserts Flat made of Cross-Linked PE
    - Size range
        - Internal Diam. 22, 28, 32, 36 mm
- Acetabular Inserts 15° Lipped made of Cross-Linked PE
    - Size range
        - Internal Diam. 28, 32, 36 mm

Summary of Technological Characteristics:
The Pantheon PFR System is substantially equivalent to the following component system 510(k)s. The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The geometries and range of available sizes are also similar. The subject and predicate devices are packaged in similar materials and are sterilized using similar methods.

- Pantheon Proximal Femur Replacement: Stryker Orthopaedics Global Modular Replacement System (GMRS®) Proximal Femoral, K023087 *(Primary Predicate)*
- Pantheon Proximal Femur Replacement: Stryker Orthopaedics Global Modular Replacement System (GMRS®) Proximal Femoral, K040749
- CoCrMo Femoral Heads: DePuy Orthopaedics M-SPEC Metal Femoral Heads, K980513
- Biolox Delta Femoral Heads: Zimmer GmbH Biolox Delta Ceramic Femoral Heads, K071535
- Acetabular Cups: Limacorporate S.p.A Delta TT Acetabular System, K112898
- Acetabular Insert: DePuy Orthopaedics Pinnacle Altrx Polyethylene Acetabular Liner, K072963
- Zimmer® Segmental System Trabecular Metal Proximal Tibial Component, Trabecular Metal Proximal Femoral Component, and additional Segment with Male/Female Taper components, K110940

Performance Testing:
The following performance testing was performed on the Pantheon Proximal Femur Reconstruction (PFR) System:

- Neck Fatigue Testing (ISO 7206-6)
- Distal Stem Fatigue Testing (ISO 7206-4:2010)
- Corrosion Testing (ASTM F1875-98)

- Post Fatigue Modular Disassembly Testing (ASTM F2009-20, ISO 7206-10:2018)
- Taper Disassembly Testing (ASTM F2009-20, ISO 7206-10:2018)
    - Axial disassembly between shafts
    - Torsional disassembly between shafts
    - Torsional disassembly between shaft and proximal body
- Range of Motion (EN ISO 21535:2017)
- Impingement Testing (ASTM F2582-20)
- Ceramic Head Burst Testing (ISO 7206-10, ASTM F2345)
- Ceramic Head Fatigue Testing (ISO 7206-10, ASTM F2345)
- Ceramic Head Post-Fatigue Burst Testing (ISO 7206-10, ASTM F2345)
- Ceramic Head Disassembly (Pull-Off) Testing (ISO 7206-10, ASTM F2009)
- Ceramic Head Rotational Stability (Torque) Testing (ISO 7206-13)
- CoCrMo Head Disassembly (Pull-Off) Testing (ASTM F2009-20)
- CoCrMo Head Rotational Stability (Torque) Testing (ISO 7206-13:2016, ISO 7206-10:2018)
- Acetabular Cup Fatigue Testing (ASTM F3090-20)
- Insert push-out Testing (ASTM F1820-13)
- Insert lever out Testing (ASTM F1820-13)
- Insert torque-out Testing (ASTM F1820-13)
- Insert Wear Testing (ISO 14242-1:2014/Amd1:2018, ISO 14242-2:2016)
- Acetabular Screw Torsion (ASTM F543)
- Acetabular Screw Driving Torque (ASTM F543)
- Acetabular Screw Pull-Out (ASTM F543)
- Acetabular Cup Deformation Testing rationale

Substantial Equivalence:

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The geometries and range of available sizes are also similar. The subject and predicate devices are packaged and sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.