June 2, 2023

Howmedica Osteonics Corp. dba Stryker Orthopaedics
Jane Guo
Senior Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K230952
Trade/Device Name: Triathlon® Total Knee System - Triathlon® Pro Posterior Stabilized (PS) Femoral Component
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: April 3, 2023
Received: April 4, 2023

Dear Jane Guo:

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,

Jesse Muir -S

Jesse Muir, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230952

Device Name
Triathlon® Total Knee System - Triathlon® Pro Posterior Stabilized (PS) Femoral Component

Indications for Use *(Describe)*
General Total Knee Arthroplasty (TKR) Indications:
• Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis, or avascular necrosis), rheumatoid arthritis or post-traumatic arthritis.
• Post-traumatic loss of knee joint configuration and function.
• Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
• Revision of previous unsuccessful knee replacement or other procedure.
• Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture-management techniques.

Additional Indications for Posterior Stabilized (PS) Components:
• Ligamentous instability requiring implant bearing surface geometries with increased constraint.
• Absent or non-functioning posterior cruciate ligament.
• Severe anteroposterior instability of the knee joint.

The Triathlon® Pro PS Femoral Components are intended for cemented use only.

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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510(k) Summary

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Date Prepared: April 3rd, 2023

Proprietary Name: Triathlon® Total Knee System – Triathlon® Pro Posterior Stabilized (PS) Femoral Component

Common Name: Total Knee Joint Replacement

Classification Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3560)

Product Codes: JWH

Legally Marketed Primary Predicate Devices to Which Substantial Equivalence is Claimed:

- The components of the Triathlon® Total Knee System:
  - Triathlon® Posterior Stabilized (PS) Femoral Component – K190402

Legally Marketed Additional Predicate Devices Used to Support Substantial Equivalence:

- The components of the Triathlon® Total Knee System:
  - Triathlon® Posterior Stabilized (PS) Femoral Component – K042993, K141056, K172326

Legally Marketed Reference Devices Used to Support Substantial Equivalence:

- Prelude™ PF Resurfacing Knee System – K123907

- Triathlon® Cruciate Retaining (CR) Femoral Component – K040267, K141056, K172326

Reason for 510(k) Submission:
The purpose of this submission is to introduce a new Triathlon® Pro Posterior Stabilized (PS) Femoral Component to the Triathlon® Total Knee System.

Device Description:
The subject Triathlon® Pro PS Femoral Component is a line extension to the existing Triathlon® Total Knee System and will be a modified version of the predicate Triathlon® PS Femoral Components. The subject component is sterile, single use, and available in sizes 1-8 and in right and left configurations. The femoral component is manufactured from Cobalt-Chromium alloy, which meets ASTM material standard F2886-17 as well as F75-18 standard requirements in its final finished form. It is intended for cemented use only.

Intended Use:
The subject PS femoral component has the same intended use as the predicate devices as specified in the 510(k) submissions for the predicate devices – the subject device is intended to be used in total knee arthroplasty and for cemented use only.

Indications:
The subject PS femoral component has the same indications for use as the predicate devices:

General Total Knee Arthroplasty (TKR) Indications:
- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis, or avascular necrosis), rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture-management techniques.

Additional Indications for Posterior Stabilized (PS) Components:
- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.
- Severe anteroposterior instability of the knee joint.

The Triathlon® Pro PS Femoral Components are intended for cemented use only.

Summary of Technological Characteristics:
The subject device will be manufactured using a low-pressure metal injection molding process (Cobalt-Chromium alloy conforming to ASTM F2886-17) as opposed to the casting process (CoCr conforming to ASTM F75-18) utilized by the predicate devices. Reference device, K123907, utilizes this same manufacturing process. The device comparisons and performance testing show that the subject Triathlon® Pro PS Femoral Component is substantially equivalent to the cited predicate Triathlon® PS Femoral Components based on

intended use, indications for use, design, material, sterilization method, biocompatibility, MR compatibility, technical and performance characteristics, and operational principles.

Non-Clinical Testing:
The following non-clinical laboratory testing and engineering analysis were performed to determine substantial equivalence:

- Material Characterization – CoCr per ASTM F2886-17 and ASTM F75-18
- Femoral Component Fatigue Testing
- Wear Testing per ISO 14243-3:2014
- Characterization of Tibiofemoral Contact Area/Contact Stress
- Characterization of Patellofemoral Contact Area/Contact Stress
- Characterization of Articulating/Bearing Surface Finish
- Characterization of Range of Motion and Constraint
- Biocompatibility evaluated per ISO 10993-1:2018
- Shelf-life validated per the following standards:
    - ISO 11607-1:2019
    - ISO 11607-2:2019
    - ASTM F1980-21
- Bacterial endotoxin testing (BET) as specified in ANSI/AAMI ST72:2019 was used for pyrogenicity testing to achieve an endotoxin limit of <20EU/Device.
- The subject Triathlon® Pro Posterior Stabilized (PS) Femoral Component has been evaluated according to the FDA guidance document entitled "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment" issued May 20, 2021 and to the standards listed below:
    - Magnetically Induced Displacement Force performed per ASTM F2052-15
    - Magnetically Induced Torque performed per ASTM F2213-17
    - Image Artifact per ASTM F2119-07(2013)
    - Heating by Radio Frequency Fields performed per ASTM F2182-19e2

Clinical Testing:
Clinical testing was not required as a basis for substantial equivalence.

Conclusion:
Based upon a comparison of the intended use, indications for use, design, material, sterilization method, biocompatibility, MR compatibility, technical and performance characteristics, and operational principles, the subject Triathlon® Pro Posterior Stabilized (PS) Femoral Component is substantially equivalent to the cited predicate Triathlon® PS Femoral Components.