January 20, 2023

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

Re: K223528
Trade/Device Name: Triathlon® Hinge Knee System
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee Joint Femorotibial Metal/Polymer Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: KRO
Dated: November 22, 2022
Received: November 23, 2022

Dear Allison Byrne:

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,

Ting Song -S

Ting Song, 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)*

K223528

Device Name
Triathlon® Hinge Knee System

Indications for Use *(Describe)*

This Rotating Hinge Knee System is intended to be implanted with bone cement for the following condition(s):
• There is destruction of the joint surfaces, with or without significant bone deformity.
• The cruciate and/or collateral ligaments do not stabilize the knee joint.
• The ligaments are inadequate and/or the musculature is weak. And/or
• Revision is required of a failed prosthesis where there has been gross instability, with or without bone loss or inadequate soft tissue.
• And/or where segmental resection and replacement of the distal femur is required.

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

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Date Prepared: November 22, 2022

Proprietary Name: Triathlon® Hinge Knee System

Common Name: Rotating Hinge Knee System
Artificial Knee System
Total Knee Joint Prosthesis

Classification Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis. (21 CFR Part 888.3510)

Product Codes: KRO

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

- The components of the Modular Rotating Hinge Knee System:
  - Modular Rotating Hinge (MRH) Knee Femoral Components – K994207, K002552
  - MRH Hinge Tibial Inserts - K994207, K002552
  - MRH Sleeve - K994207, K002552
  - MRH Tibial Baseplate - K994207, K002552
  - MRH Tibial Bearing Component - K994207, K001548, K001957, K002552
  - MRH Bumper components - K994207, K002552
  - MRH Knee Femoral Distal Block – K994207

Legally Marketed Additional Predicate Devices Used to Support Substantial Equivalence:

- The components of the Triathlon® Total Knee System:
  - Triathlon® Total Stabilized (TS) Femoral Components – K070095, K141056, K172326
  - Triathlon® TS Plus Inserts – K070095, K072221, K141056, K172326, K172634
  - Triathlon® Universal Baseplate – K053514, K141056, K172326
  - Triathlon® Femoral Distal Augments – K070095, K141056, K172326
  - Triathlon® Tibial Augments – K053514, K141056, K172326

Legally Marketed Reference Devices Used to Support Substantial Equivalence in terms of biocompatibility:

- Triathlon® Tritanium Metal Back Patella – K132624, K141056, K172326
- Triathlon® Posterior Stabilized (PS) Tibial Insert – K031729, K141056, K172326
- Osteonics® Omnifit® X Plus Cemented Hip Stem - K983226, K153345

Reason for 510(k) Submission:

The purpose of this submission is to introduce a line extension to the Triathlon® Total Knee System, specifically a new Triathlon® Hinge Knee (THK) System.

Device Description:

The subject THK System is a line extension to the existing Triathlon® Knee System and will be a modified version of the predicate Modular Rotating Hinge (MRH) Knee System and Triathlon® Total Knee System. The THK System is a tricompartmental knee system consisting of a new hinge femoral component and a new tibial bearing component connected by a set of previously cleared MRH bushings and an MRH axle (K994207, K002552). A new bumper locks this assembly. This assembly provides motion through the MRH axle/bushings combination in the flexion/extension plane. The articulation between the bearing surfaces on the underside of the new tibial bearing component and a new hinge tibial insert provides motion in the rotating plane. The hinge tibial insert is assembled to a new revision tibial baseplate which incorporates a longitudinal bore to accept a new tibial sleeve or previously cleared MRH tibial sleeve (K994207, K002552). Optional new distal femoral and tibial augments are available to fill bone defects.

The THK System is designed to provide varus/valgus stability throughout the range of motion, internal/external rotation about the tibial axis, constraint by the bearing surface radius on the tibial bearing component, and an extensive range of size, modularity, and resection options. The subject THK System consists of:

- Hinge Femoral Components in six sizes and in left and right configurations
- Revision Tibial Baseplates in seven sizes
- Hinge Inserts in seven sizes and five thicknesses – each hinge insert is packaged with a standard sleeve subcomponent

- Tibial Bearing Components in three sizes
- Bumper inserts in neutral and three degree flexion options
- Revision Tibial Augments in eight sizes, two thicknesses and in right medial/left lateral and right lateral/left medial options
- Femoral Distal Augments in six sizes and two thicknesses.

The components of the subject THK System are sterile, single-use devices intended for cemented use only. They can be used with previously cleared Modular Rotating Hinge (MRH) Knee components (K994207, K002552), the Global Modular Replacement System (GMRS) (K023087), and Triathlon® Knee System components (K172634, K172326, K190991, K143396, K141056, K132624, K070095, K061521, K053514, K052917, K051948, K051146, K040267).

Intended Use:
The component of the subject THK System have the same intended use as those specified in the 510(k) submissions for the components of the predicate devices listed. The THK System components are sterile, single-use devices intended for cemented use in primary and revision total knee arthroplasty. The THK System is intended to be used for the treatment of a severely unstable knee, particularly with the loss of collateral support in both primary and revision cases. The THK System can also be incorporated into implants for distal femoral and total femoral replacements performed for the treatment of bone tumors. It is a partially constrained prosthesis with limited rotational capability, which allows more natural motion and reduces torque on the fixation.

Indications:
This Rotating Hinge Knee System is intended to be implanted with bone cement for the following condition(s):

- There is destruction of the joint surfaces, with or without significant bone deformity.
- The cruciate and/or collateral ligaments do not stabilize the knee joint.
- The ligaments are inadequate and/or the musculature is weak. And/or
- Revision is required of a failed prosthesis where there has been gross instability, with or without bone loss or inadequate soft tissue.
- And/or where segmental resection and replacement of the distal femur is required.

Summary of Technological Characteristics:
The device comparisons and performance testing show that the components of the subject THK System are substantially equivalent to those of the predicate MRH Knee and Triathlon® Total Knee System based on intended use, indications for use, design, materials and sterilization method, performance characteristics, and operational principles.

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

- Materials Characterization – UHMWPE
- Triathlon® Hinge Femoral Component Fatigue Testing
- Fatigue testing of the Revision Tibial Baseplate Components per ASTM F1800-19e1
- Fatigue testing of the Tibial Bearing components
- Tibial Bearing Component Chair Rise Testing
- Shear fatigue analysis of the baseplate/insert locking mechanism
- Full construct fatigue worst-case analysis
- Wear Analysis per ISO 14243-1 and ISO 14243-3
- Analysis of contact area/contact stress – Tibial Bearing/Hinge Insert Components
- Patellofemoral Contact Area/Contact Stress and Constraint Analysis
- Range of motion and rotational freedom analysis
- Revision Tibial Augment and Locking Strength Analysis
- Femoral Distal Augment and Locking Strength Analysis
- Strength analysis for Hinge Femur Component's boss/stem and Revision Tibial Baseplate Component's boss/stem junctions
- Biocompatibility evaluated per ISO 10993-1:2020
- Shelf-life validated per the following standards:
    - ISO 11607-1:2019
    - ISO 11607-2:2019
    - ASTM F1980-21
    - Testing performed per the following methods:
        - ASTM F1886/F1886M-16
        - ASTM F88/88M-21
        - ASTM F2096-11(2019)
- Bacterial endotoxin testing (BET) as specified in ANSI/AAMI ST72:2019 was used for pyrogenicity testing to achieve an endotoxin limit of < 20EU/Device.

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, materials and sterilization method, performance characteristics, and operational principles, the components of the subject THK System are substantially equivalent to those of the predicate devices identified in this premarket notification.