July 25, 2025

Howmedica Osteonics Corp. dba Stryker Orthopaedics
Niyati Dave
Staff Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K251665
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: May 25, 2025
Received: May 30, 2025

Dear Niyati Dave:

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,

Lixin Liu -S

Lixin Liu, PhD
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251665

Device Name
Triathlon® Hinge Knee System

Indications for Use *(Describe)*
Triathlon® 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.

When used with MRH femur and/or MRH tibial baseplate replacement indicated in revision of an existing prosthesis:
• Revision is required of a failed prosthesis where there has been gross instability, with or without bone loss or inadequate soft tissue.

When used with compatible GMRS components:
• Where segmental resection and/or replacement of femur and/or proximal tibia 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: July 25, 2025

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 Device to which Substantial Equivalence is Claimed:

- Triathlon® Hinge Knee System; Triathlon® Revision Insert X3® - K230416

Legally Marketed Additional Predicate Devices Used to Support Substantial Equivalence:

- Triathlon® Total Knee System - K053514, K141056, K172326
- GMRS Tibial Rotating Component - K023087, K222056
- MRH Tibial Rotating Component- K994207, K002552

Reason for 510(k) Submission:

The purpose of this Traditional 510(k) Premarket Notification is to support the marketing clearance of the new Triathlon® Small Proximal Tibial Bearing Component and Triathlon® End Cap as part of the Triathlon® Hinge Knee (THK) System. Additionally, this submission expands the compatibility of the THK system for use with components of the existing Modular Rotating Hinge (MRH) Knee System and Global Modular Replacement System (GMRS).

Device Description:

The subject THK components are a line extension of the previously cleared Triathlon® Hinge Knee System (K223528, K230416). The THK System (K223528, K230416) is a tricompartmental knee system consisting of a stemmed femoral component and a stemmed tibial bearing component connected by a set of previously cleared MRH or THK Bushings and an MRH or THK Axle (K994207, K002552, K223528, K230416). A bumper locks this assembly. This assembly provides motion through the MRH or THK Axle/Bushings combination in the flexion/extension plane. The articulation between the bearing surfaces on the underside of a tibial bearing component and a tibial insert provides motion in the rotating plane. A hinge tibial insert is assembled to a Triathlon® Hinge Revision Tibial Baseplate that

incorporates a longitudinal bore to accept a previously cleared MRH Tibial Sleeve (K994207, K002552) or Triathlon Tibial Sleeve (K223528, K230416). Optional distal femoral and tibial augments are available to fill bone defects.

The subject Triathlon® Hinge Small Proximal Tibial Bearing Component and Triathlon® End Cap are sterile, single use devices intended for cemented use only and are being added to the previously cleared THK system (K223528, K230416) as an extension. They can be used with previously cleared MRH Knee components (K994207, K002552), GMRS (K023087, K222056), and Triathlon® Knee System components (K172634, K172326, K190991, K143393, K141056, K132624, K070095, K061521, K053514, K052917, K051948, K051146, K040267).

Intended Use:

The subject components of THK System have the same general intended use as those specified in the 510(k) submissions for the predicate devices listed. The intended use statement has been updated to add reference to the proximal tibial replacement and to clarify that the use with GMRS/MRH is for knee replacement procedures as well as bone tumors.

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 is also compatible with the GMRS and MRH systems for distal femoral and total femoral replacements and/or proximal tibia 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.

The Indications for Use have been updated to reflect the additional compatibilities, and for clarity.

Indications:

Triathlon® Hinge Knee System:

Triathlon® 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.

When used with MRH femur and/or MRH tibial baseplate replacement indicated in revision of an existing prosthesis:

- Revision is required of a failed prosthesis where there has been gross instability, with or without bone loss or inadequate soft tissue.

When used with compatible GMRS components:

- Where segmental resection and/or replacement of femur and/or proximal tibia is required

Summary of Technological Characteristics:

The subject Triathlon Hinge Small Proximal Tibial Bearing Component is a sterile, single-use device and manufactured from the same material ASTM F1537, as that of the legally marketed predicate Triathlon Hinge Tibial Bearing Components (K223528, K230416). The subject component design is also based on the predicate device, and the only differences are smaller AP and ML widths to prevent the overhanging on the tibial insert during internal/external rotation of the tibia. The subject component utilizes the same basic principles of operation as the cited predicate devices.

The subject Triathlon End Cap is a sterile, single-use device that has the same material (ASTM F1537) and similar design as that of the predicate Triathlon 50mm Cemented Stems (K053514, K141056, K172326). The subject device is identical to the existing subcomponent Triathlon Universal Baseplate End Cap (5560-S-016) cleared in K053514; the subject End Cap will now

be packaged as a standalone saleable part. The subject component utilizes the same basic principles of operation as those of the cited predicate devices.

Non-Clinical Testing:

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

- Triathlon Hinge Bearing Component varus/valgus fatigue
- Triathlon Hinge Bearing Component chair rise testing
- Triathlon Hinge full construct fatigue
- Wear test rationale for new constructs
- Analysis of contact area/contact stress and constraint analysis
- Range of motion and rotational freedom analysis – tibia/femoral (all modes of rotation – flexion/extension, internal/external, varus/valgus, and translation – medial/lateral, proximal/distal, anterior/posterior) (ASTM F1223-20)
- Total Femur construct compatibility and Triathlon Hinge Bushing/Axle compatibility analysis with legacy bearing components
- Triathlon Revision Baseplate-End Cap locking strength analysis
- Triathlon End Cap tightening analysis
- Triathlon End Cap load carrying capacity rationale
- Triathlon End Cap stability analysis
- MRI Testing
    - Magnetically induced displacement force test (ASTM F2052-15)
    - Magnetically induced torque test (ASTM F2213-17)
    - Image artifact tests (ASTM F2119-07, reapproved 2013)
    - RF Heating evaluation (ASTM F2182-191ae)
- 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, technical and performance characteristics, and operational principles, the subject THK System components are substantially equivalent to the respective predicate devices identified in this premarket notification.