May 19, 2023

Stryker
Allison Byrne
Senior Specialist, Regulatory Affairs
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K230416
Trade/Device Name: Triathlon® Hinge Knee System; Triathlon® Revision Insert X3®
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee Joint Femorotibial Metal/Polymer Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: KRO, JWH
Dated: April 19, 2023
Received: April 20, 2023

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,

Jesse Muir -S

Jesse Muir, PhD
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)*

K230416

Device Name

Triathlon® Hinge Knee System

Indications for Use *(Describe)*

Triathlon® Hinge Knee System:
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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K230416

Device Name
Triathlon® Revision Insert X3®

Indications for Use *(Describe)*
Triathlon® Revision Insert X3®:
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 Total Stabilizer (TS) 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.
• Severe instability of the knee secondary to compromised collateral ligament integrity or function.

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)

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510(k) Summary

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Mahwah, NJ 07430

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Date Prepared: May 18th, 2023

Proprietary Name: Triathlon® Hinge Knee System, Triathlon® Revision Insert X3®

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)

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

Product Codes: KRO, JWH

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

- Modular Rotating Hinge Knee (MRH) – K002552, K994207, K223069

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

- Triathlon® Total Stabilized (TS) Plus Insert X3® – K172326, K141056, K072221, K070095, K172634
- Triathlon® Hinge Knee System – K223528

Legally Marketed Reference Devices Used to Support Substantial Equivalence in terms of Magnetic Resonance (MR) Imaging:

- Global Modular Replacement System – K222056

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

Additional Legally Marketed Reference Devices Used to Support Substantial Equivalence in terms of non-clinical performance:

- Duracon Total Stabilizer Insert – K973164
- Duracon Baseplate – K915512

Reason for 510(k) Submission:
The purpose of this Traditional 510(k) Premarket Notification supports the marketing clearance for the new Triathlon® Bushing and Axle (Standard Assembly Pack) components as part of the Triathlon® Hinge Knee System and for the new Triathlon® Revision Insert X3® component of the Triathlon® Total Knee System. There have been no previous submissions for these subject devices.

This Traditional 510(k) Premarket Notification is also being submitted to support market clearance for a labeling modification to add MRI Conditional Labeling to the Triathlon® Hinge Knee System components cleared in 510(k) Premarket Notification K223528.

Device Description:
The previously cleared Triathlon® Hinge Knee (THK) System (K223528) is a tricompartmental knee system consisting of a stemmed femoral component and a stemmed tibial bearing component connected by a set of Modular Rotating Hinge (MRH) bushings and MRH axle (K222056, K002552, K994207). A bumper locks this assembly. This assembly provides motion through the MRH axle/bushing combination in the flexion/extension plane. The articulation between bearing surfaces on the underside of a tibial bearing component and a hinge tibial insert provide motion in the rotating plane. A hinge tibial insert is assembled to a revision tibial baseplate which incorporates a longitudinal bore to accept a Triathlon® tibial sleeve or an MRH tibial sleeve. Optional distal femoral and tibial augments are available to fill bone defect. The Instructions for Use and package labels for the THK components are being updated to bear the MR Conditional symbol and MR Conditional parameters.

The subject Triathlon® Bushing and Axle (Standard Assembly Pack) contains sterile, single-use devices that are being added to the previously cleared THK System (K223528) as an alternate option to MRH bushings and MRH axle to connect a stemmed femoral component and a stemmed tibial bearing component and provide motion through the flexion/extension plane.

This premarket notification also introduces the subject Triathlon® Revision Insert X3®, which is a sterile, single-use device that is intended for use in a total knee arthroplasty with the previously cleared Triathlon® Revision Tibial Baseplate (K223528) and Triathlon® TS Femoral Component (K172326, K141056, K070095) as part of the Triathlon® Total Knee System. The subject insert is available in seven sizes, and each size is available in seven different thicknesses. The subject insert is packaged together with Cobalt-Chrome (CoCr) stabilizer pin and filler bushing subcomponents that are assembled intraoperatively. The subject insert is assembled to the previously cleared Triathlon® Revision Baseplate (K223528), which incorporates a longitudinal bore to accept the filler bushing subcomponent. The stabilizer pin is inserted through the subject Triathlon® Revision Insert X3® and extends into filler bushing assembled within the Triathlon® Revision Tibial Baseplate to provide additional stability in the insert post.

Intended Use:
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.

The Triathlon® Revision Insert X3® component is a sterile, single use device intended for use in total knee arthroplasty with the Triathlon® TS Femoral component (K172326, K141056, K070095) and the Triathlon® Revision Tibial Baseplate (K223528) as part of the Triathlon® Total Knee System.

Indications for Use:
<u>Triathlon® Hinge Knee System:</u>
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.

<u>Triathlon® Revision Insert X3®:</u>
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 Total Stabilizer (TS) 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.
- Severe instability of the knee secondary to compromised collateral ligament integrity or function.

Summary of Technological Characteristics:
The device comparisons and performance testing show that the subject components of the THK System, the subject Triathlon® Bushing and Axle (Standard Assembly Pack) and the subject Triathlon® Revision Insert X3® are substantially equivalent to those of the respective predicate THK system, MRH Knee, and Triathlon® TS Plus Insert X3® based on intended use, indications for use, design, materials and sterilization method, 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:

- Materials Characterization – UHMWPE
- Contact Area/Contact Stress Analysis – Triathlon® Revision Insert X3®
- Wear Analysis
- Range of Motion and Constraint Analysis – Triathlon® Revision Insert X3®
- Varus/Valgus Fatigue Testing – Triathlon® Revision Insert X3®
- Locking Mechanism Analysis – Triathlon® Revision Insert X3®
- Normal Level Walking Analysis – Triathlon® Revision Insert X3®
- Full Construct Fatigue Test
- Fretting Corrosion Analysis
- Biocompatibility evaluated per ISO 10993-1:2020. Please note, there is no impact to the biocompatibility of the components of the Triathlon® Hinge Knee System that were previously cleared in K223528.
- 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 devices have been submitted as MR Conditional. In alignment with FDA guidance document titled “Testing and Labeling Medical Devices for Safety in the Magnetic

Resonance (MR) Environment," issued May 20, 2021, evaluations were performed according to the standards listed below:

- Magnetically Induced Displacement Force performed per ASTM F2052-15, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- Magnetically Induced Torque performed per ASTM F2213-17, Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
- Heating by Radio Frequency Fields performed per ASTM F2182-19, Standard Test Method for Measurement of Radio Frequency Induced Heating on or Near Passive Implants During Magnetic Resonance Imaging
- Image Artifact performed per ASTM F2119-07 (2013), Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants

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 components of the subject Triathlon® Hinge Knee System and the Triathlon® Revision Insert X3® component are substantially equivalent to those of their respective predicate devices identified in this premarket notification.