August 15, 2019

Howmedica Osteonics Corp. (aka Stryker Orthopaedics)
Dipan Lad
Senior Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K190991
Trade/Device Name: Triathlon Tritanium Central Femoral Cone Augment, Triathlon Femoral Distal Augment
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH
Dated: July 19, 2019
Received: July 22, 2019

Dear Dipan Lad:

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,

For CAPT Raquel Peat, PhD, MPH, USPHS
Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190991

Device Name
Triathlon Total Knee System

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.

The Triathlon® Tritanium® Total Knee System components are indicated for both uncemented and cemented use.

The Triathlon® Total Knee System beaded and beaded with Peri-Apatite components are intended for uncemented use only.

The Triathlon® All Polyethylene tibial components are indicated for cemented use only.

Additional Indications for Posterior Stabilized (PS) and 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.

Additional Indications for Total Stabilizer (TS) Components:

- Severe instability of the knee secondary to compromised collateral ligament integrity or function.

Indications for Bone Augments:

- Painful, disabling joint disease of the knee secondary to: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis, complicated by the presence of bone loss.
- Salvage of previous unsuccessful total knee replacement or other surgical procedure, accompanied by bone loss.

Additional Indications for Cone Augments:

- Severe degeneration or trauma requiring extensive resection and replacement
- Femoral and Tibial bone voids
- Metaphyseal reconstruction

The Triathlon Tritanium® Cone Augment components are intended for cemented or 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.

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

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510(k) Summary

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Date Prepared: April 11, 2019

Proprietary Name: Triathlon® Tritanium® Central Femoral Cone Augment
Triathlon® Femoral Distal Augment

Common Name: Total Knee Joint Replacement

Classification Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis. (21 CFR Section 888.3565)

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

Product Codes: MBH, JWH

Legally Marketed Device to which Substantial Equivalence is Claimed:

Triathlon® Tritanium® Femoral and Tibial Cone Augments – K143393, K172326
Triathlon® Femoral Distal Augments – K070095, K141056, K172326

Device Description:

Triathlon® Tritanium® Central Femoral Cone Augment:

The subject Triathlon® Tritanium® Central Femoral Cone Augment is an extension of the Triathlon® Total Knee System product line and is intended to be used as an optional accessory component in primary or revision Total Knee Arthroplasty. It is a sterile, single-use device that is composed of commercially pure titanium (raw material per ASTM F1580, processed material per ASTM F67).

The subject Triathlon® Tritanium® Central Femoral Cone Augment is designed to be used with the Triathlon® Total Stabilizer (TS) femoral components and is compatible with other Triathlon® Total Knee System components. The Triathlon® Tritanium® Central Femoral Cone Augments are intended to be cemented to the respective Triathlon® femoral components and are intended for fixation within the distal femur with or without bone cement. Triathlon® Tritanium® Central Femoral Cone Augments are intended to be used where there is a femoral metaphyseal defect secondary to trauma, failed previous prosthesis, or severe degeneration.

Triathlon® Femoral Distal Augment:

The subject Triathlon® Femoral Distal Augment is a modified version of the Triathlon® Femoral Distal Augment that is a component of the Triathlon® Total Knee System product line. It is intended to be used as an optional accessory component in primary or revision Total Knee Arthroplasty. It is a sterile, single-use device that is composed of either Cobalt-Chrome-Molybdenum (Co-Cr-Mo per ASTM F75) or Cobalt-Chrome (per ASTM F1537). These are the same materials as the predicate devices identified in this 510(k) premarket notification.

The subject Triathlon® Femoral Distal Augment is designed to be used with the Triathlon® TS or Triathlon® Posterior Stabilizer (PS) femoral components and is compatible with other Triathlon® Total Knee System components. The subject device is intended for attachment to the respective Triathlon® TS or PS femoral components with a locking screw; the augment-femoral component construct is intended to be cemented into the prepared distal femur. The Triathlon®

Femoral Distal Augments are intended to be used in cases with severely inadequate medial or lateral femoral bone stock requiring additional fixation of the femoral components.

Intended Use:

Triathlon® Tritanium® Central Femoral Cone Augment:

The subject Triathlon® Tritanium® Central Femoral Cone Augment has the same intended use as that specified in the cleared 510(k) Premarket Notifications for the respective predicate devices listed in this 510(k) premarket notification. This intended use is listed below.

The Triathlon® Tritanium® Central Femoral Cone Augment is intended for use in primary or revision Total Knee Arthroplasty where there is a femoral metaphyseal defect secondary to trauma, failed previous prosthesis, or severe degeneration. The Triathlon® Tritanium® Central Femoral Cone Augment is intended to be affixed to the mating femoral component using bone cement. The cones are intended for fixation as an assembled construct in the distal femur, with or without bone cement.

Triathlon® Femoral Distal Augment:

The subject Triathlon® Femoral Distal Augment has the same intended use as that specified in the cleared 510(k) Premarket Notifications for the respective predicate devices listed herein. Intended use of the modified device, as described in its labeling, has not changed as a result of the modification(s).

Indications for Use:

The subject Triathlon® Tritanium® Central Femoral Cone Augment and the subject Triathlon® Femoral Distal Augment have the same Indications for Use as those specified in the predicate devices' cleared 510(k) Premarket Notifications. The Indications for Use are as follows:

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.

The Triathlon® Tritanium® Total Knee System components are indicated for both uncemented and cemented use.

The Triathlon® Total Knee System beaded and beaded with Peri-Apatite components are intended for uncemented use only.

The Triathlon® All Polyethylene tibial components are indicated for cemented use only.

Additional Indications for Posterior Stabilized (PS) and 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.

Additional Indications for Total Stabilizer (TS) Components:

- Severe instability of the knee secondary to compromised collateral ligament integrity or function.

Indications for Bone Augments:

- Painful, disabling joint disease of the knee secondary to: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis, complicated by the presence of bone loss.
- Salvage of previous unsuccessful total knee replacement or other surgical procedure, accompanied by bone loss.

Additional Indications for Cone Augments:

- Severe degeneration or trauma requiring extensive resection and replacement
- Femoral and Tibial bone voids
- Metaphyseal reconstruction

The Triathlon® Tritanium® Cone Augment components are intended for cemented or cementless use.

Summary of Technological Characteristics:

Device comparisons and performance testing show that the subject Triathlon® Tritanium® Central Femoral Cone Augment and the subject Triathlon® Femoral Distal Augment are substantially equivalent to the respective predicate devices in terms of intended use, indications, design, materials, performance characteristics and operational principles.

Non-Clinical Testing:

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

Triathlon® Tritanium® Central Femoral Cone Augment:

- Characterization of the Chemistry, Physical and Mechanical Properties of the Triathlon® Tritanium® Central Femoral Cone Augment – the porous surface meets the requirements outlined in the FDA guidance documents, "Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone Or Bone Cement," dated April 28, 1994.
- Impaction Test & Morphology Analysis of the Triathlon® Tritanium® Central Femoral Cone Augment
- Triathlon® Tritanium® Central Femoral Cone Augment Micromotion
- Cantilever Fatigue Test Analysis
- Torque Test Analysis
- MRI Analysis - the subject Triathlon® Tritanium® Central Femoral Cone Augments were evaluated to determine if they created a new worst-case for image artifact, magnetically induced torque, magnetically induced displacement, and RF induced heating. These subject devices do not create a new worst-case as compared to those Triathlon® Total Knee components previously cleared in 510(k) Premarket Notification K172326. The subject devices are considered to be MR Conditional.

Triathlon® Femoral Distal Augment:

- Tolerance analysis
- Fatigue strength analysis
- MRI Analysis - the subject Triathlon® Femoral Distal Augments were evaluated to determine if they created a new worst-case for image artifact, magnetically induced torque, magnetically induced displacement, and RF induced heating. These subject devices do not create a new worst-case as compared to those Triathlon® Total Knee components previously cleared in 510(k) Premarket Notification K172326. The subject devices are considered to be MR Conditional.

Clinical Testing:

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

Conclusion:

Based upon a comparison of the intended use, materials, summary of technological characteristics, and preclinical testing, the subject Triathlon® Tritanium® Central Femoral Cone Augment and the subject Triathlon® Femoral Distal Augment are substantially equivalent to the respective predicate devices identified in this premarket notification.