May 13, 2020

Howmedica Osteonics Corp.
Nora O'Connor
Staff Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K200782
Trade/Device Name: Triathlon Posterior Stabilized Femoral Component - beaded with Peri-Apatite, Triathlon Cruciate Retaining Femoral Component - beaded with Peri-Apatite
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MBH
Dated: March 20, 2020
Received: March 26, 2020

Dear Nora O'Connor:

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, Ph.D., R.A.C.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200782

Device Name
Triathlon® Posterior Stabilized Femoral Component - beaded with Peri-Apatite
Triathlon® Cruciate Retaining Femoral Component - beaded with Peri-Apatite

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 Tibial Baseplate and Tritanium Metal-Backed Patella 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 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.

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510(k) Summary

Sponsor	Stryker Orthopaedics 325 Corporate Drive Mahwah, NJ 07430
Contact Person	Nora O'Connor Staff Regulatory Affairs Specialist Stryker Ireland Osteonics Tullagreen Building IDA Business & Technology Park Carrigtwohill, Cork Munster, T45 HE42 Ireland +353 21 453 2529
Alternate Contact	Paula McCarthy Regulatory Affairs Manager Howmedica International S. DE R.L Raheen Business Park Limerick Munster, V94 X6T4 Ireland +353 872 824 403
Date Prepared:	March 20, 2020
Proprietary Name:	Triathlon® Posterior Stabilized Femoral Component - beaded with Peri-Apatite Triathlon® Cruciate Retaining Femoral Component - beaded with Peri-Apatite
Common Name:	Total Knee Joint Replacement

Classification Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis 21 CFR §888.3565

Product Codes: MBH

Legally Marketed Device to Which Substantial Equivalence is Claimed:
Triathlon® Posterior Stabilized Femoral Component - beaded with Peri-Apatite and Triathlon® Cruciate Retaining Femoral Component - beaded with Peri-Apatite - K051380, K141056 and K172326.

Device Description:
The Triathlon® Posterior Stabilized (PS) Femoral Component - beaded with Peri-Apatite (PA) and Triathlon® Cruciate Retaining (CR) Femoral Component - beaded with Peri-Apatite (PA) are components of the Triathlon® Total Knee System previously cleared via 510(k)s K051380, K141056 and K172326. The subject Triathlon® Femoral Components are components of the Triathlon® Total Knee System and are used in total knee arthroplasty procedures. The subject Triathlon® Femoral Components are available in 8 different sizes and in left and right configurations that are anatomically suited to the left or right knee. The subject Triathlon® Femoral Components are manufactured from cast cobalt-chrome-molybdenum alloy (ASTM F75) with a cobalt-chrome-molybdenum alloy (ASTM F75) double layer porous coating (beading) on the femoral fixation surface. Additionally, the subject Triathlon® Femoral Components are coated with Peri-Apatite (ASTM F1185).

The design and materials of the subject Triathlon® Femoral Components are identical to the predicate Triathlon® Femoral Components cleared via 510(k)s K051380, K141056 and K172326. The proposed modification is to introduce automated equipment for the first and second porous coating (beading) application process steps for the subject Triathlon® Femoral Components. There are no modifications proposed to the other components of the Triathlon® Total Knee System previously cleared via 510(k)s K051380, K141056 and K172326. The subject Triathlon® Femoral Components will have the same performance specifications as the predicate Triathlon® Femoral Components cleared via 510(k)s K051380, K141056 and K172326.

Intended Use:
The subject Triathlon® Femoral Components have the same intended use as the predicate Triathlon® Femoral Components.

Indications for Use:

The subject Triathlon® Femoral Components have the same Indications for Use as the predicate Triathlon® Femoral Components. The indications for use include:

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 Tibial Baseplate and Tritanium Metal-Backed Patella 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 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 non-clinical testing show that the subject Triathlon® PS Femoral Component - beaded with PA and Triathlon® CR Femoral Component - beaded with PA are substantially equivalent to the respective Triathlon® Femoral Components in terms of intended use, indications for use, design, materials, performance characteristics, and operational principles.

Non-Clinical Testing:

The following non-clinical laboratory testing was performed to determine substantial equivalence:

Testing for porous coating type a. beaded, sintered cobalt-chrome coatings on a cobalt-chrome substrate as per FDA guidance document, "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement," dated April 28, 1994. Based upon the testing completed, the subject Triathlon® Femoral Components are substantially equivalent to the respective predicate Triathlon® Femoral Components. The proposed modification does not affect safety or effectiveness.

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, performance characteristics, and operational principles, the subject Triathlon® PS Femoral Component - beaded with PA and Triathlon® CR Femoral Component - beaded with PA are substantially equivalent to the respective predicate Triathlon® Femoral Components identified in this premarket notification. The proposed modification does not affect safety or effectiveness.