Stryker Orthopaedics
Shahrir Alam
Senior Regulatory Affairs Specialist
325 Corporate Dr.
Mahwah, New Jersey 07430

November 16, 2017

Re: K172634
Trade/Device Name: Triathlon® X3® UHMWPE Tibial Inserts and Patellar Components
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: August 30, 2017
Received: September 1, 2017

Dear Shahrir Alam:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K172634

Device Name: Triathlon® X3® UHMWPE Tibial Inserts and Patellar Components

Indications for Use:

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 TS Cone Augment components are intended for cemented or cementless use.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Sponsor	Stryker Orthopaedics 325 Corporate Drive Mahwah, NJ 07430
Contact Person	Shahrir Alam Senior Regulatory Affairs Specialist Howmedica Osteonics Corp 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-6223; Fax: (201) 831-3223
Alternate Contact	Margaret Klippel Sr. Principal Regulatory Affairs Project Manager, Regulatory Affairs Howmedica Osteonics Corp 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5559; Fax: (201)-831-4559
Date Prepared:	August 31, 2017
Proprietary Name:	Triathlon® X3® UHMWPE Tibial Inserts and Patellar Components
Common Name:	Total Knee Joint Replacement
Classification Name:	Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis. (888.3565) Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (888.3560)
Product Codes:	MBH, JWH

Legally Marketed Devices to Which Substantial Equivalence is Claimed:

- Triathlon® PS and CR X3® UHMWPE Tibial Inserts (K051146)
- Triathlon® Symmetric and Asymmetric X3® UHMWPE Patellar Components (K051146)
- Triathlon® CS X3® UHMWPE Tibial Inserts (K063423)
- Triathlon® TS X3® UHMWPE Tibial Inserts (K072221)

Legally Marketed Reference Devices Used to Support Substantial Equivalence:

- Triathlon® PS Tibial Inserts (K031729)
- Triathlon® Symmetric and Asymmetric Patellar Components (K040267)
- Triathlon® CR Tibial Inserts (K042883)
- Triathlon® CS Tibial Inserts (K063423)
- Triathlon® TS Tibial Inserts (K072221)

Device Description: The subject Triathlon® X3® UHMWPE Tibial Inserts and Patellar Components are a modified version of the predicate Triathlon® X3® UHMWPE Tibial Inserts and Patellar Components. The device designs are identical to the predicate devices which are available in the posterior stabilized (PS), cruciate retaining (CR), condylar stabilizing (CS) and total stabilizing (TS) designs for the tibial inserts, and the symmetric and asymmetric designs for the patellar components. The subject inserts and patellar components will have a different method of terminal sterilization (ethylene oxide) and will be formed by consolidating Type 1 (GUR1020) resin via conventional methods which meet the specifications of ASTM F648. Like the predicate devices, the subject Triathlon® X3® CR, CS, PS and TS+ tibial inserts will contain a Cobalt Chromium locking wire as per ASTM F90, and the Triathlon TS+ tibial insert will also additionally contain a Cobalt Chromium tibial support pin as per ASTM F1537.

Intended Use:
The subject devices have the same intended use as those specified in the 510(k) clearances for the predicate devices listed.

Indications for Use:

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 TS Cone Augment components are intended for cemented or cementless use.

Summary of Technological Characteristics: The subject Triathlon® X3® Tibial Inserts and Patellar Components are identical in intended use, indications, design, and operational principles as the predicate device. The subject devices are different from the predicate device in its terminal sterilization method. The subject devices are terminally sterilized by Ethylene Oxide, whereas the predicate device is sterilized using Gas Plasma. Consolidation of X3® polyethylene can be performed via conventional methods. The X3® UHMWPE continues to meet the same ASTM F648 specification.

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

1) Material Testing per ASTM F648, ASTM F2565, and Draft FDA Guidance, “Characterization of Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices” (February 12, 2016).
2) Biocompatibility Testing per ISO 10993-1:2009, ISO 10993-7:2008, and FDA Guidance, “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (June 16, 2016)
3) Ethylene Oxide Sterilization Validation per ISO 11135:2014
4) Wear Test based on ISO/DIS 14243-3:2014
5) Static Shear Insert Baseplate Locking Mechanism Test
6) Single Axis Fatigue Test
7) Multi-Axis Fatigue Test
8) Bacterial endotoxin testing (BET) as specified in ANSI/AAMI ST72:2011 was used for pyrogenicity testing to achieve an Endotoxin limit of <20 EU/Device

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

Conclusion: The Triathlon® X3® UHMWPE Tibial Inserts and Patellar Components are substantially equivalent to the predicate devices identified in this premarket notification.

Device comparison showed that the proposed device is substantially equivalent in intended use, materials, and performance characteristics to the predicate device. The proposed modification does not affect safety or effectiveness.