Stryker Orthopaedics
Margaret Crowe Klippel
Sr. Principal Regulatory Affairs Project Manager
325 Corporate Drive
Mahwah, New Jersey 07430

February 2, 2018

Re: K173849
Trade/Device Name: Triathlon Total Knee System
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: December 18, 2017
Received: December 19, 2017

Dear Margaret Klippel:

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,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K173849

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 TS 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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K173849

510(k) Summary

Sponsor Stryker Orthopaedics
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Date Prepared: December 15, 2017

Proprietary Name: Triathlon Total Knee System

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 Device to Which Substantial Equivalence is Claimed:

- Triathlon X3 ETO Tibial Inserts and Patellar Components – K172634
- Triathlon CR N2Vac Tibial Inserts – K040267, K042883, K051380, K141056, K172326
- Triathlon PS N2Vac Tibial Inserts – K031729, K051380, K141056, K172326
- Triathlon CS Total Knee System X3 and N2Vac Tibial Inserts – K063423, K141056, K172326

Device Description:
The subject Triathlon Intermediate Tibial Inserts will be available in the following configurations:

- Cruciate Retaining (CR) – intermediate thicknesses of inserts (10mm, 12m, 14mm) will be added to the previously cleared size range of 9mm, 11mm, 13mm, 16mm and 19mm

- Cruciate Substituting (CS) – intermediate thicknesses of inserts (10mm, 12mm and 14mm) will be added to the previously cleared size range of 9mm, 11mm, 13mm, 16mm, 19mm, 22mm and 25mm
- Posterior Stabilizing (PS) - intermediate thicknesses of inserts (10mm, 12mm and 14mm) will be added to the previously cleared size range of 9mm, 11mm, 13mm, 16mm, 19mm, 22mm and 25mm

The design of these inserts are identical to the predicate devices in terms of condylar geometry, post dimensions (in PS design) and locking wire feature. The inserts will be available in X3 ETO, and N2Vac styles.

Additionally, MR Conditional labeling is being added for the subject intermediate thickness inserts as well as those X3 ETO tibial inserts and patellar components previously cleared in premarket notification K172634.

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

Indications:

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 ETO and N2Vac Intermediate Tibial Inserts are identical in intended use, indications, materials, terminal sterilization method and operational principles as the predicate devices. The subject intermediate tibial inserts are different from the predicate device in terms of thicknesses – these intermediate inserts will be available in 10mm, 12mm, and 14mm.

Non-Clinical Testing:
Material characterization of the X3 ETO material and the N2Vac material has been previously presented in premarket notifications for predicate devices. The material properties are unchanged for these predicates – this previous characterization was provided in support of substantial equivalence.

The design of the subject Triathlon intermediate insert thicknesses was analyzed, and it was concluded that these new insert thicknesses do not create a new worst case for minimum or maximum material thickness, contact area/stress, moments and forces required for disassociation. Previous testing performed for the predicate devices is representative of the subject intermediate thicknesses. These tests include:

1) Material Testing per ASTM F648, ASTM F2565, and FDA Guidance, “Characterization of Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices” (February 12, 2016).
2) Biocompatibility Testing per EN ISO 10993-1:2010 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 EN 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

The subject Triathlon intermediate thickness tibial inserts, as well as the Triathlon X3 ETO tibial inserts and patellar components cleared in K172634, were evaluated to determine if these devices 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 K172326. The subject devices are considered to be MR Conditional. This analysis reviewed testing performed to the following ASTM standards:

- Magnetically Inducted Displacement Force – performed per ASTM F2052-15, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the MR Environment

- Magnetically Induced Torque – performed per ASTM F2213-06 (Reapproved 2011), Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the MR Environment

- Image Artifact – performed per ASTM F2119-07 (Reapproved 2013), Standard Test Method for Evaluation of MR Image Artifacts from passive Implants

- Heating by RF Fields per ASTM F2182-11a, Standard Test Method for Measurement of Radio Frequency Induced Heating near Passive Implants during MR Imaging

Bacterial endotoxin testing (BET) as specified in ANSI/AAMI ST72:2011 was used for pyrogenicity testing on the subject devices 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® Knee System X3 ETO and N2Vac Tibial Inserts 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 modifications do not affect safety or effectiveness.