August 22, 2019

Stryker Orthopaedics
Margaret Crowe Klippel
Senior Principal RA Project Manager
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K190402
Trade/Device Name: Triathlon Total Knee System- Additional 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: July 25, 2019
Received: July 29, 2019

Dear Margaret Crowe 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. 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)*
K190402

Device Name
Triathlon Total Knee System

Indications for Use *(Describe)*
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.

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.

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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)*
K190402

Device Name
Triathlon Tritanium Tibial Baseplate

Indications for Use *(Describe)*
Indications for Use:

General Total Knee Arthroplasty (TKR) Indications:
• Painful, disabling joint disease of the knee resulting from: non-inflammatory 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 General Total Knee Arthroplasty (TKR) Indications specific to the PS implant:
• Ligamentous instability requiring implant bearing surface geometries with increased constraint
• Absent or non-functioning posterior cruciate ligament
• Severe anteroposterior instability of the knee joint

The Triathlon Tritanium Tibial Baseplates are indicated for both cemented and uncemented use.

Type of Use *(Select one or both, as applicable)*

[X] 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
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Mahwah, NJ 07430

Contact Person Margaret Klippel
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Phone: (201) 972-9164

Date Prepared: February 18, 2019

Proprietary Name: Triathlon® Total Knee System – Additional Components

Common Name: Total Knee Joint Replacement

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

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

Product Codes: MBH, JWH

Legally Marketed Device to Which Substantial Equivalence is Claimed:

Triathlon Cruciate Retaining (CR) Femoral Component – K040267, K141056, K172326
Triathlon Posterior Stabilizing (PS) Femoral Component – K042993, K141056, K172326
Triathlon Primary Cemented Tibial Baseplate – K031729, K141056, K172326
Triathlon Tritanium Tibial Baseplate – K123486, K141056, K172326
Triathlon X3 ETO Tibial Inserts (CR, Condylar Stabilizing [CS], and PS) – K172634, K173849
Triathlon N2Vac Tibial Inserts (CR, CS, and PS) – K031729, K040267, K063423, K141056, K172326, K173849

Device Description:
The additional components being added to the Triathlon Total Knee System are:

- Size 0 Cruciate Retaining Femoral Component (cemented use)

- Size 0 Primary Cemented Tibial Baseplate
- Size 0 Tritanium Tibial Baseplate for cemented/cementless use
- Size 0 CR, CS, and PS Tibial Inserts in X3 ETO and N2Vac
- New PS Femoral Component with modified intercondylar PS box (cemented use)
- New PSR (Posterior Stabilizing Rotation) tibial insert in sizes 0-8 in X3 ETO

Additionally, engineering analyses and finite element analyses were presented to document the range of motion available with the Triathlon Total Knee System.

Intended Use:
The subject Triathlon Femoral components, Primary tibial baseplate, and tibial inserts 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.

The subject Triathlon Tritanium Tibial Baseplate share the same indications for use as the existing Triathlon Tritanium Tibial Baseplates:

General Total Knee Arthroplasty (TKR) Indications:

- Painful, disabling joint disease of the knee resulting from: non-inflammatory 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 General Total Knee Arthroplasty (TKR) Indications specific to the PS implant:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint
- Absent or non-functioning posterior cruciate ligament
- Severe anteroposterior instability of the knee joint

The Triathlon Tritanium Tibial Baseplates are indicated for both cemented and uncemented use.

Summary of Technological Characteristics:
The subject Triathlon components are identical in terms of intended use, indications for use, and materials and terminal sterilization methods as compared to the predicate devices. The size 0 subject components differ from the previously cleared predicate devices in terms of overall dimensions – the reduced dimensions are intended to allow the devices to be used in smaller patients. The new PS Femoral component features a reduced PS intercondylar box to allow less

bone removal anteriorly. The new PSR insert is designed to offer less resistance to internal/external rotation in deep flexion in patients who can achieve this range of motion.

Non-Clinical Testing:

The following non-clinical testing was presented:

- Fatigue testing of the femoral components
- Fatigue testing of the tibial baseplate components per ASTM F1800-12
- Static shear testing of the insert-baseplate locking mechanism
- Contact area/contact stress analysis of the tibial inserts
- Range of constraint of the tibial inserts
- Range of motion analyses
- Ethylene Oxide Sterilization Validation per EN ISO 11135:2014

Previous testing performed to characterize the Tritanium surface was reviewed, and found to be applicable to the subject Triathlon Tritanium Tibial Baseplate.

The subject Triathlon components 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.

Additionally, contact area/contact stress and range of motion analysis was presented to support the update in range of motion for the Triathlon system.

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® Total Knee System – Additional Components are substantially equivalent to the predicate devices identified in this premarket notification.

Device comparison showed that the proposed devices are substantially equivalent in intended use, materials, and performance characteristics to the predicate devices. The proposed modifications do not affect safety or effectiveness.