July 10, 2020

Howmedica Osteonics Corp. dba Stryker Orthopaedics
Shikha Khandelwal
Principal Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K201343
Trade/Device Name: Triathlon® Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH, MBH
Dated: May 15, 2020
Received: May 20, 2020

Dear Shikha Khandelwal:

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)*

K201343

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 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) 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.

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.

510(k) Summary

Sponsor Stryker Orthopaedics
325 Corporate Drive
Mahwah, NJ 07430

Contact Person Shikha Khandelwal, PhD
Principal Regulatory Affairs Specialist
Stryker Orthopaedics
324 Corporate Drive
Mahwah, NJ 07430 USA
(201) 831-6921
Shikha.khandelwal@stryker.com

Date Prepared: May 15, 2020

Proprietary Name: Triathlon® Total Knee System

Common Name: Total Knee Joint Replacement

Classification Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis 21 CFR §888.3560
Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis 21 CFR §888.3565

Product Codes: JWH, MBH

Legally Marketed Device to Which Substantial Equivalence is Claimed:
Primary predicate: Triathlon® Total Knee System cleared most recently via K172326 and K190402
Secondary predicates: Zimmer Persona® Personalized Knee System cleared via K172524, Medacta GMK Sphere Knee cleared via K173890

Device Description:
This submission covers Mako Total Knee Application-compatible components of the Triathlon® Total Knee System intended for use with the Mako System during a total knee

arthroplasty. These include cruciate-retaining (CR), condylar stabilized (CS) and posterior stabilized (PS) components, tibial baseplates and TS tibial inserts. Triathlon® Total Knee System PSR tibial inserts are being reviewed for compatibility with the Mako Total Knee Application under K193515. The Triathlon® Total Knee System components have been previously cleared in prior 510(k) submissions and are commercially available. The Mako Total Knee Application-compatible Triathlon® Total Knee System components are manufactured from the following materials: Cobalt Chromium Alloy, Titanium Alloy, Commercially Pure Titanium, Ultra-High Molecular Weight Polyethylene and Calcium Phosphate.

Purpose of the submission:

The purpose of this submission is the addition of an individualized alignment pre-operative planning methodology for Triathlon® Total Knee System components used in conjuction with the Mako System. The proposed individualized alignment pre-operative planning method aims to recreate the patient's joint line through symmetric measured resection medially and laterally on both the femur and tibia off the native bone anatomy.

Intended Use:

The subject devices have the same intended use as the primary predicate devices.

Indications for Use:

The subject devices have the same Indications for Use as the primary predicate devices:

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) 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.

Summary of Technological Characteristics:
The addition of an individualized alignment pre-operative planning methodology does not impact the following technological characteristics of the subject Triathlon® Total Knee System compared to the primary predicate devices:

- Intended use – Identical to primary predicate
- Indications for Use – Identical to primary predicate
- Design – Identical to primary predicate
- Materials – Identical to primary predicate
- Operational principles – Identical to predicate

Summary of Non-clinical Performance Data :
The following non-clinical laboratory assesments have been previously performed:

- Femoral fatigue
- Tibial baseplate fatigue
- Range of constraint
- Tibiofemoral and patellofemoral contact area/contact stress
- Patellofemoral subluxation/tracking
- Knee alignment clinical outcomes data review
- Cadaveric validation

These assesments demonstrate that the performance characteristics of the subject Triathlon® Total Knee System components are equivalent to the performance characteristics of the predicate devices.

Clinical Testing:
Clinical testing is 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® Total Knee System components are substantially equivalent to the respective predicate devices identified in this premarket notification. The proposed modification does not affect safety or effectiveness.