DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 13, 2015

Stryker Orthopaedics
Ms. Margaret Klippel
Associate Strategic Regulatory Affairs Manager
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K143393
Trade/Device Name: Triathlon® Tritanium® Cone Augments
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: November 25, 2014
Received: November 26, 2014

Dear Ms. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143393

Device Name
Triathlon® Tritanium® Cone Augments

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Sponsor Stryker Orthopaedics
325 Corporate Drive
Mahwah, NJ 07430

Contact Person Margaret Klippel
Associate Strategic Regulatory Affairs Manager
Howmedica Osteonics Corp
Margaret.klippel@stryker.com
Ph: 201-831-5559
Fax: 201-831-4559

Date Prepared: November 25, 2014

Proprietary Name: Triathlon® Tritanium® Cone Augments

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 Predicate Devices to Which Substantial Equivalence is Claimed:

- Zimmer Trabecular Metal Knee System Augments (K053340)
- DePuy Universal Gription™ TF Cones (Knee) – DePuy Orthopaedics (K100391)

Legally Marketed Reference Devices Used to Support Substantial Equivalence:

- Triathlon® Tritanium® Tibial Baseplate (K123486)
- Triathlon® Tritanium® Metal Backed Patella (K132624)

Device Description:

The Triathlon® Tritanium® Cone Augment is an extension of the Triathlon® Total Knee System product line intended to be used as an optional accessory component in primary or revision Total Knee Arthroplasty. It is a sterile, single-use device that is compatible for use with other Triathlon® Total Knee System components. The Triathlon® Tritanium® Cone Augment is composed of commercially pure titanium (raw material per ASTM F1580, processed material per ASTM F67).

The subject device is designed to be used with the Triathlon® TS femoral components and Triathlon® Universal baseplates and is compatible with other Triathlon® Total Knee System

components. The cones are intended to be cemented to the respective Triathlon femoral and/or tibial component, and are intended for fixation within the proximal tibia or distal femur with or without bone cement. Tritanium Femoral and Tibial Cones are intended to be used where there is a femoral and/or tibial metaphyseal defect secondary to trauma, failed previous prosthesis, or severe degeneration.

There are three designs of Triathlon Tritanium Cone Augments:

- Femoral Cone Augments
- Symmetric Tibial Cone Augments
- Asymmetric Tibial Cone Augments

Intended Use:
The Triathlon® Tritanium® Cone Augment is intended for use in primary or revision total knee arthroplasty where there is a femoral and/or tibial metaphyseal defect secondary to trauma, failed previous prosthesis, or severe degeneration. The Triathlon Tritaium Cone Augment is intended to be affixed to the mating femoral and/or tibial component using bone cement. The cones are intended for fixation as an assembled construct in the distal femur and/or proximal tibia, with or without bone cement.

Indications:
The Triathlon Tritanium Cone augments have the same Indications for Use as the Triathlon TS Total Knee System – additional indications for cone augments are noted below.

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® Tritanium® Cone Augment components are intended for cemented or cementless use.

Summary of Technological Characteristics: Device comparisons and performance testing show that the Triathlon® Tritanium® Cone Augment is substantially equivalent to its predicate in terms of intended use, indications, design, materials, performance characteristics and operational principles.

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

- Cantilever Fatigue Testing in accordance with ASTM F1800- Cone augments survived ten million cycles of clinically relevant loading without failure -

- Torque Testing was performed to establish that the cone augments are able to withstand clinically relevant torque loads

- Plastic Deformation of Cone Augments – cones were metallographically examined in the post-impacted condition – indicated porous surface can withstand impaction without loss of coating integrity

- Micromotion of Triathlon Tibial Cone Augments – comparative testing was performed to evaluate the initial stability of the Triathlon Tibial Cone construct within the prepared

simulated tibial cavity during a simulated stair descent activity. Micromotion of the baseplate/cone construct with respect to the polyurethane foam constructs used to simulate the proximal tibia was recorded for Triathlon cone constructs and compared to the micromotion of the Zimmer Trabecular metal cone constructs (predicate device). This testing indicates that the Triathlon Tibial Cone Augments are at least equivalent to the Zimmer Trabecular Metal Cones in their ability to resist micromotion.

- Triathlon Tritanium Femoral Cone Augment Micromotion - comparative testing was performed to evaluate the initial stability of the Triathlon Femoral Cone construct within the prepared simulated femoral cavity during a normal walking profile. This testing indicates that the Triathlon Femoral Cone Augment is at least equivalent to the Zimmer Femoral Cone Augment in the ability to resist micromotion.

- Characterization of the Physical Properties of the Triathlon Tritanium Cone Augment – this testing established that the porous coating meets the requirements outlined in the FDA guidance documents, "Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone Or Bone Cement", April 28, 1994, and FDA Guidance Document, "Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses, Guidance for Industry and FDA", January 16, 2003.

- Characterization of the Material Chemistry of the Triathlon Tritanium Cone Augment - the results of the chemical analysis illustrates that the material meets the requirements set forth in ASTM F67 for Grade 4 unalloyed titanium material, and is similar to a reference device

- Characterization of the Mechanical Properties of Triathlon Tritanium Cone Augments - testing was performed to characterize the mechanical properties of cone augments. Surface treated test coupons processed identically to the final device were used. The subject devices met or exceeded the pre-established performance criteria, and are similar to the reference device in terms of performance criteria.

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

Conclusion: Based upon a comparison of intended use, materials, summary of technological characteristics, and preclinical testing, the Triathlon® Tritanium® Cone Augment is substantially equivalent to the predicate devices identified in this premarket notification.