Howmedica Osteonics Corp. aka Stryker Orthopaedics
Valerie Giambanco
Senior Staff Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

October 24, 2019

Re: K191358
Trade/Device Name: Trident II Acetabular System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH, KWZ, LZO, JDI, MEH
Dated: September 24, 2019
Received: September 26, 2019

Dear Valerie Giambanco:

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 Vesa Vuniqi
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K191358

Device Name
Trident® II Acetabular System

Indications for Use *(Describe)*

Indications for Use

• Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
• Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
• Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
• Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

When used with MDM® Liners

• Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.
• Dislocation risks

When used with Constrained Liner

• The Trident® Constrained Acetabular Insert is indicated for use in primary and revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intraoperative instability.

The Trident® II Acetabular Shells are indicated for cementless use only.

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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510(k) Summary of Safety and Effectiveness:
Trident® II Acetabular System

Sponsor Stryker Orthopaedics
325 Corporate Drive
Mahwah, NJ 07430

Contact Person Valerie Giambanco
Principal Regulatory Affairs Specialist
Stryker Orthopaedics
Valerie.giambanco@stryker.com
Ph: 201-831-6275

Date Prepared: Sept 24, 2019

Proprietary Name: Trident® II Acetabular System
Total Hip Joint Replacement

Classification Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis. (888.3358)
Hip joint metal/polymer constrained cemented or uncemented prosthesis. (888.3310)
Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (888.3353)
Hip joint metal/polymer semi-constrained cemented prosthesis (888.3350)

Product Codes: LPH, KWZ, LZO, JDI, MEH

Legally Marketed Predicate Devices to Which Substantial Equivalence is Claimed:

- Trident® II Acetabular System (K171768)

- Acetabular Dome Hole Plugs (K942809)

Reference Devices Supporting Substantial Equivalence:

- Osteonics Secur-Fit HA Generation II [aka Trident® PSL] Acetabular Shells (K983382, K143085)

Device Description:

The Trident® II Acetabular Shells, 6.5mm Low Profile Hex Screws and dome hole plugs are sterile, single-use devices that are intended for cementless fixation into a prepared acetabulum for either primary or revision Total Hip Arthroplasty. The Trident® II Acetabular Shells are intended to be used with existing Trident® polyethylene inserts, Trident® Constrained Acetabular Inserts, MDM® liners and both new and existing surgical instruments. The purpose of this Special 510(k) is to add an additional dome hole plug option for use with the Trident® II Acetabular System**.**

Intended Use:

The subject Trident® II Acetabular System is intended for use in total hip arthroplasty and is intended for either primary or revision Total Hip Arthroplasty.

Indications:

The subject Trident® II Acetabular System maintains the same indications for use as those cleared in K171768.

Indications for Use:

• Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, posttraumatic arthritis or late stage avascular necrosis.

• Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.

• Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

• Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

When used with MDM® Liners:

• Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

• Dislocation risks

When used with Constrained Liners:

• The Trident® Constrained Acetabular Insert is indicated for use in primary and revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intraoperative instability.

The Trident® II Acetabular Shells are indicated for cementless use only.

Summary of Technological Characteristics: Device comparisons and performance testing show that the Trident® II Acetabular System when used with the Acetabular Dome Hole Plug is substantially equivalent to the predicates in terms of intended use, indications, design, materials, performance characteristics and operational principles.

Non-Clinical Testing: No new non-clinical testing was performed. Analyses have demonstrated equivalence in dimensions and MR evaluation. Prior bacterial endotoxin testing (BET) as specified in ANSI/AAMI ST72:2011 was referenced for pyrogenicity testing to achieve an Endotoxin limit of < 20EU/Device.

Conclusion: Based upon a comparison of intended use, materials, technological characteristics, and tolerance and MR analysis, the Trident® II Acetabular System when used with the Acetabular Dome Hole Plug is substantially equivalent to the predicate devices identified in this premarket notification.