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

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

October 2, 2017

Re: K171768
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, JDI, KWZ, LZO, MEH
Dated: August 31, 2017
Received: September 1, 2017

Dear Ms. 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. 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 (DICE) 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 (DICE) 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,

Mark N. Melkerson -S

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)*
K171768

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.

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

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510(k) Summary

Sponsor	Stryker Orthopaedics 325 Corporate Drive Mahwah, NJ 07430
Contact Person	Valerie Giambanco Staff Regulatory Affairs Specialist Stryker Orthopaedics Valerie.giambanco@stryker.com Ph: 201-831-6275 Fax: 201-831-3275
Date Prepared:	Sept 27, 2017
Proprietary Name: **Common 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 Tritanium® Acetabular Shells and 6.5 mm Low Profile Hex Screws (K161569)
- Osteonics Secur-Fit™ HA Generation II [aka Trident PSL] Acetabular Shells (K983382, K143085)
- Dome and Screw Hole Plugs (K920868)

Legally Marketed Reference Devices Used to Support Substantial Equivalence:

- Accolade II (K103479, K120578)
- Stryker Orthopaedics Total Hip Systems Labeling Update (K153345)

- Restoration Anatomic Cup (K142462, K151264)

Device Description:

The Trident® II Acetabular Shells, 6.5mm Low Profile Hex Screws and Hex Dome Hole Plug 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 System is an extension of the Trident System product line and features the same locking mechanism as the current Trident® and Trident® II Tritanium® product lines. 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 Trident® II Tritanium® implant consists of a unique configuration of both solid and porous sections that are simultaneously built using a Laser Rapid Manufacturing (LRM) method of additive manufacturing, applying Stryker's proprietary Tritanium® In-Growth Technology. Tritanium® is a novel highly porous titanium material designed for biological fixation. The Trident® II PSL® Clusterhole HA and Trident® II Clusterhole HA Acetabular Shells feature hydroxylapatite coating over a Commercially Pure Titanium plasma sprayed surface for cementless fixation.

The subject devices are manufactured from the following materials:

Product	Material
Trident® II PSL® Clusterhole HA Trident® II Clusterhole HA	Ti6Al4V ELI Alloy per ASTM F620, ASTM F136 Commercially Pure (CP) Titanium per ASTM F1580 Hydroxylapatite per ASTM F1185
Trident® II Tritanium® Solidback Trident® II Tritanium® Clusterhole Trident® II Tritanium® Multihole	Ti6Al4V Alloy per ASTM F1472
Hex Dome Hole Plug	Ti6Al4V ELI Alloy per ASTM F136
6.5mm Low Profile Hex Screw	Ti6Al4V ELI Alloy per ASTM F136

Intended Use:

The 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 Trident® II Acetabular System has the same Indications for Use as the Trident® II Tritanium® Acetabular Shells.

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 is substantially equivalent to the predicates in terms of intended use, indications, design, materials, performance characteristics and operational principles.

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

- Push out (ASTM F1820)
- Lever out (ASTM F1820)
- Torque out (ASTM F1820)
- Range of Motion Analysis
- Acetabular Shell Fatigue Testing
- Fretting Evaluation of the MDM liner
- Bone Screw Testing (ASTM F543)
- Plastic Deformation
- Material Chemistry

- Characterization of the Chemistry, Physical and Mechanical Properties of the porous surface –this testing established that the porous surface 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. The titanium plasma spray surface was also characterized according to the methods described in this guidance document.
- Bacterial endotoxin testing (BET) as specified in ANSI/AAMI ST72:2011 was used for pyrogenicity testing to achieve an Endotoxin limit of < 20EU/Device.
- MRI Analysis: Non-clinical testing as outlined in the FDA guidance document "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment – Guidance for Industry and FDA Staff", dated December 11, 2014 was conducted to characterize the compatibility of Trident II Acetabular System and compatible total hip passive implants in the MR environment. FDA draft guidance "Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices – Draft Guidance for Industry and FDA Staff", dated June 29, 2015 was also consulted for the heating evaluations performed. Testing was performed according to the standards listed below:
    - Magnetically Induced Displacement Force – performed per ASTM F2052-06 and ASTM F2052-14, 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

  The labeling of the Trident II Acetabular System and compatible total hip implants has been modified to include the MR conditional symbol, and to provide the parameters under which a patient who has the device can be safely scanned.

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 Trident® II Acetabular System is substantially equivalent to the predicate devices identified in this premarket notification.