



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

Stryker Orthopaedics
Valerie Giambanco
Staff Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

October 14, 2016

Re: K161569

Trade/Device Name: Trident® II Tritanium® Acetabular Shells and 6.5 mm Low Profile
Hex Screws

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: August 31, 2016

Received: September 1, 2016

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. 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,


Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K161569

Device Name: Trident[®] II Tritanium[®] Acetabular Shells and 6.5mm Low Profile Hex Screws

Indications for Use:

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 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 Tritanium[®] Acetabular Shells are indicated for cementless use only.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

510(k) Summary

Sponsor Stryker Orthopaedics
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Date Prepared: October 14, 2016

Proprietary Name: Trident® II Tritanium® Acetabular Shells and 6.5 mm Low Profile Hex Screws

Common Name: 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:

- Tritanium® Acetabular Shell System (K081171) [Shell]
- Restoration Acetabular Cup (K943549) [Screw]

Legally Marketed Reference Devices Used to Support Substantial Equivalence:

- Tritanium® PL Cage (K152304)
- Trident® Tritanium® PST® Acetabular Shells (K142606)
- Vitallium Cancellous Bone Screw (K944213)

- Osteolock Acetabular Cup & Bone Screw (K903362)
- Osteonics® HA Generation II Acetabular Component System (K983382)
- Restoration Anatomic Shell (K151264)

Device Description:

The Trident® II Tritanium® Acetabular Shell and 6.5mm Low Profile Hex Screws 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 Tritanium® Acetabular Shell is an extension of the Trident System product line and features the same locking mechanism as the current Trident® Tritanium® product line. The Trident® II Tritanium® Acetabular Shell is intended to be used with existing Trident® polyethylene inserts, MDM® liners and existing surgical instruments.

The subject device is manufactured from Ti-6Al-4V ELI alloy. The implant consists of a unique configuration of both solid and porous structures that are simultaneously built using a Laser Rapid Manufacturing (LRM) method of additive manufacturing, applying Stryker's proprietary Tritanium® In-Growth Technology.

There are three designs of Trident® II Tritanium® Acetabular Shells:

- Solidback (sizes 42A-66H)
- Clusterhole (sizes 42A-66H)
- Multihole (sizes 42A-72J)

The new compatible 6.5mm Low Profile Hex Screws feature a hex geometry and are manufactured from wrought Ti-6Al-4V ELI. The new screws range in lengths from 15-80mm.

Intended Use:

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

Indications:

The Trident® II Tritanium® Acetabular Shells have the same Indications for Use as the Tritanium® Acetabular Shells – with the additional specific indications noted for MDM® and Constrained Insert compatibility, as identical to the recently cleared Restoration® Anatomic Shell (K151264). The optional compatible bone screws share the same indications as the mating acetabular shell.

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 Tritanium Acetabular Shells are indicated for cementless use only.

Summary of Technological Characteristics: Device comparisons and performance testing show that the Trident® II Tritanium® Acetabular Shell and 6.5mm Low Profile Hex Screw are 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 to determine substantial equivalence:

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

- Bacterial endotoxin testing (BET) was used for pyrogenicity testing to achieve an acceptable endotoxin limit as specified in ANSI/AAMI ST72:2011.

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 Tritanium® Acetabular Shell and the 6.5mm Low Profile Hex Screw are substantially equivalent to the predicate devices identified in this premarket notification.