



Food and Drug Administration  
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Silver Spring, MD 20993-0002

Stryker Orthopaedics  
Ms. Allison Ling  
Regulatory Affairs Specialist  
325 Corporate Drive  
Mahwah, New Jersey 07430

August 10, 2015

Re: K151264  
Trade/Device Name: Restoration Anatomic Shell  
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  
Dated: July 8, 2015  
Received: July 10, 2015

Dear Ms. Ling:

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 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)

Unknown K151264 (page 1 / 1)

Device Name

Restoration Anatomic Shell

Indications for Use (Describe)

- 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 Restoration® Anatomic Shell is 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**

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**Date Prepared:** May 12th, 2015

**Proprietary Name:** Restoration Anatomic Shell

**Common Name:** Total Hip Joint Replacement

**Classification Name:** Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis. (888.3358)

**Product Codes:** LPH

**Legally Marketed Device to Which Substantial Equivalence is claimed:**

- Primary: Restoration Anatomic Shell (K142462)
- Secondary: Trident Porous Titanium Acetabular Shell (K010170)

**Device Description:**

The Restoration Anatomic Shell is a sterile, single-use device that is intended for cementless fixation into a prepared acetabulum for either primary or revision Total Hip Arthroplasty. The subject device substrate is manufactured from Ti-6Al-4V ELI alloy and has a porous CP-Ti coating. The materials, design features and screw hole locations of the Restoration Anatomic

Shell are identical to the primary predicate device cleared in K142462. The purpose of this submission is to add compatibility of Trident Polyethylene Liners and clarify the indications for use for specific compatible liners.

**Intended Use:** The Restoration Anatomic Shell is intended for use in total hip arthroplasty and is intended for either primary or revision Total Hip Arthroplasty.

**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 Restoration Anatomic Shell is indicated for cementless use only.

**Summary of Technological Characteristics:** Device Comparisons show that the Restoration Anatomic Shell is substantially equivalent to its predicates in terms of intended use, indications, design, materials, performance characteristics and operational principles.

**Non-Clinical Testing:** The following non-clinical laboratory testing has been provided to determine substantial equivalence:

- 1) Lever-out Test of a Trident Polyethylene Liner in a Trident Shell
- 2) Push-out Test of a Trident Polyethylene Liner in a Trident Shell
- 3) Lever-out Test of a Trident Constrained Polyethylene Liner in a Trident Shell
- 4) Range of Motion for the Trident 0° Constrained Acetabular Liner

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

**Conclusion:** The Restoration Anatomic Shell is substantially equivalent to the predicate devices identified in this premarket notification.