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K040412
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510(k) Summary of Safety and Effectiveness for the TRIDENT® "T" SHELLS

Proprietary Name:	Trident® "T" Acetabular Shells
Common Name:	Artificial Hip Components
Classification Name and Reference	Hip joint, metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prostheses, 21 CFR §888.3353 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis 21 CFR §888.3358
Regulatory Class:	Class II
Device Product Code:	87 MEH - prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate, 87 LZO - prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented 87 LPH - prosthesis, hip, semi-constrained, metal/polymer, porous uncemented
For Information contact:	Ginny Stamberger Regulatory Affairs Specialist Stryker Orthopaedics 325 Corporate Drive Mahwah, New Jersey 07432 Phone: (201) 831-5467 Fax: (201) 831-6038 E-Mail: Ginny.Stamberger@stryker.com
Date Summary Prepared:	February 17, 2004

Identification of Predicates

1. K010170 - Trident® Porous Titanium
2. K013475 - Trident® Porous Titanium

3. K983502 - Osteonics Secur-Fit-AD Generation II Acetabular Components
4. K983382 - formerly designated as Osteonics Generation II Acetabular Components
5. K013676 - Trident® AD and AD/HA Hemispherical Acetabular Shells

Device Description

The subject devices are identical to their corresponding predicate devices, except that they feature thicker walls. Consequently, for each shell size (except the smallest, which remains unchanged) the subject Trident® "T" Shells will be compatible with a liner one size smaller than that used for the predicate Trident® designs. In addition, to accommodate the thicker walls, the screw holes were minimally shifted (not more than 4 degrees measured off the center of the shell) so as not to run into each other on the inner radius of the shell.

Intended Use:

The Trident® "T" Acetabular Shells are single-use devices intended for cementless fixation within the prepared acetabulum. They are compatible with Trident® polyethylene acetabular bearing inserts. If additional fixation is desired, the dome screw holes, if present, have been designed to accept Stryker Orthopaedics 6.5mm or 5.5mm bone screws.

Indications

- 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 inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Substantial Equivalence:

Intended Use

The subject Trident® "T" Shells retain the same intended uses and same indications for use as the cited predicate Trident® Acetabular Shells.

Materials

The subject Trident® "T" Shells are manufactured from the same materials as their corresponding predicate Trident® Acetabular Shells.

Design

The subject Trident® "T" Shells retain the same designs as their corresponding predicate Trident® Acetabular Shells with the following exceptions: The subject devices (except for the smallest size, which was unmodified) feature thicker walls. As a consequence of the thicker

walls, each shell now accepts an insert that is one size smaller than what is used in the corresponding predicate Trident® System Shells. To accommodate the added thickness, the screw hole locations were shifted minimally so as not to run into each other on the inner radius of the shell. No single shift was more than 4 degrees measured off the center of the shell. These design modifications do not raise new questions of safety or effectiveness.

Testing

A study was performed to compare the deflection experienced by the subject and predicate devices. The study demonstrated that the thicker wall design of the subject devices results in: 1) less deflection (upon implantation into the acetabulum) than in some predicate shell designs, and 2) about the same deflection as seen in other predicate shell designs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 5 2004

Ms. Ginny Stamberger
Regulatory Affairs Specialist
Stryker Orthopaedics
325 Corporate Drive
Mahwah, New Jersey 07432

Re: K040412
Trade/Device Name: Trident® "T" Acetabular Shells
Regulation Number: 21 CFR 888.3358, 21 CFR 888.3353
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prothesis
Regulatory Class: II
Product Code: LPH, LZO, MEH
Dated: April 27, 2004
Received: April 28, 2004

Dear Ms. Stamberger:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K040412

Device Name: Trident® "T" Acetabular Shells

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

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040412