K062419 1/2

stryker Howmedica OSTEONICS

325 Corporate Drive
Mahwah, NJ USA 07430

510(k) Summary of Safety and Effectiveness for the Trident® Large Diameter Acetabular Inserts

NOV 15 2006

Proprietary Name:	Trident® Large Diameter Acetabular Inserts
Common Name:	Hip Prosthesis
Classification Name and Reference	Hip Joint, Metal/Ceramic/Polymer, Semi-Constrained, Cemented or Nonporous Uncemented Prosthesis 21 CFR §888.3350 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis 21 CFR §888.3358 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis 21 CFR §888.3353
Regulatory Class:	Class II
Device Product Code:	87 LZO - Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented 87 LPH - Prosthesis Hip, Semi-Constrained, Porous Coated, Uncemented 87 MEH - Prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calicum-phosphate 87 JDI - Prosthesis, hip, semi-constrained, metal/polymer, cemented

K062419 2/2

For Information contact: Tiffani Rogers
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Date Summary Prepared: August 17, 2006

Device Description

The proposed acetabular inserts are Ultra High Molecular Weight polyethylene devices that range thickness from 3.8mm to 12.6mm measured at 34° from the axis of symmetry. The subject inserts include Trident® Large Diameter acetabular inserts, which will be available in 40mm and 44mm inner diameter (ID), and accommodate Howmedica Osteonics' 40mm and 44mm cobalt chrome femoral heads (K061434). The sizes 28 through 36 inner diameter inserts accommodate previously cleared Howmedica Osteonics' femoral heads. The polyethylene liners are compatible with the Trident® line of acetabular shells.

Intended Use:

The Trident® Large Diameter Acetabular Inserts are intended for the replacement of the bearing and articulating surfaces of the acetabulum to relieve pain, and the restriction of motion.

These subject devices are provided sterile and designed for single use only, and are intended for use in patients indicated for total hip arthroplasty. The components may be used for primary and revision applications.

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 in the acetabulum.

Substantial Equivalence:

The Trident® large diameter acetabular inserts are substantially equivalent to Howmedica Osteonics' Trident® Acetabular Inserts, K033716 and Inter-Op Durasul Acetabular System cleared by Sulzer Orthopaedics, K002575.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Howmedica Osteonics Corp.
% Ms. Tiffani Rogers
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

NOV 15 2006

Re: K062419
Trade/Device Name: Trident® Large Diameter Acetabular Inserts
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Codes: LPH, JDI, LZO, MEH
Dated: August 17, 2006
Received: August 18, 2006

Dear Ms. Rogers:

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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1/1

510(k) Number (if known): K062419

Device Name: Trident® Large Diameter Acetabular Inserts

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

Prescription Use ___X___ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K062419