K061654 (pg 1 of 2)

Special 510(k) Summary of Safety and Effectiveness: Line Extension to the Trident® Constrained Acetabular Insert

JUL - 7 2006

Proprietary Name:	Trident® Constrained Acetabular Insert
Common Name:	Constrained Hip Prosthesis
Proposed Regulatory Class:	Class II
Classification:	21 CFR § 888.3310 - Prosthesis, Hip, Constrained, Cemented or Uncemented, Metal/ Polymer
Device Product Code:	87 KWZ

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Date Summary Prepared: May 15, 2006

K061654 (pg 2 of 2)

Device Description

The Trident® Constrained Acetabular Insert is a specific insert designed to accept a Stryker UHR® bipolar head. The bipolar head is preassembled to the insert and securely retained by a titanium alloy retaining ring. This submission details two separate modifications to the predicate Trident® Constrained Acetabular Insert. The first modification is described as the subject Trident® 0° Constrained Acetabular Insert. The subject Trident® 0° Constrained Acetabular Insert has a neutral (0°) face instead of the 10° face on the predicate Trident® Constrained Acetabular Insert. The second modification is described as the subject Trident® All-Poly Constrained Acetabular Insert. The subject Trident® All-Poly Constrained Acetabular Insert has a neutral (0°) face instead of the 10° face on the predicate Trident® Constrained Acetabular Insert and a modified external geometry to allow for cement fixation.

Indications for Use

The Trident® Constrained Acetabular Insert is intended for use as a component of a total hip prosthesis in primary or revision patients at a high risk of hip dislocation due to a history of dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease or intraoperative instability.

Substantial Equivalence

The features of the subject components are substantially equivalent to the predicate devices, the Trident® 10° Constrained Acetabular Insert (P960047), the Howmedica Osteonics Contemporary Cup (K982670) and the Biomet Freedom™ Constrained Acetabular Insert (K030047), based on similarities in intended use, materials and design. Mechanical testing and analysis demonstrates substantial equivalence of the subject components to the predicate devices in regards to mechanical strength. In addition, the intended use, material, manufacturing methods, packaging, and sterilization of the predicate Trident® insert and subject components are identical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 7 2006

Howmedica Osteonics Corp.
c/o Mr. Joseph Viola
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K061654
Trade/Device Name: Trident® Constrained Acetabular Insert
Regulation Number: 21 CFR 888.3310
Regulation Name: Hip joint metal/polymer constrained cemented or uncemented prosthesis
Regulatory Class: II
Product Code: KWZ
Dated: May 15, 2006
Received: June 13, 2006

Dear Mr. Viola:

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 (301) 443-6597 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

510(k) Number (if known): K061654

Device Name: Trident® Constrained Acetabular Insert

Indications For Use:

- The Trident® Constrained Acetabular Insert is intended for use as a component of a total hip prosthesis in primary or revision patients at a high risk of hip dislocation due to a history of dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease or intraoperative instability.

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)

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

510(k) Number K061654