AUG 4 2000

510(k) Summary

K001449

Name and Address of the Sponsor:	Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Terry Sheridan Powell
Date of Summary Preparation:	May 4, 2000
Proprietary Name:	Trident Acetabular Shells: PS
Common Name:	Artificial Hip Replacement Components - Acetabular
Classification Name and Reference:	Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented or Non-Porous Uncemented Prosthesis 21 CFR §888.3353

Predicate Device Identification

- Trident Acetabular Shells (K983502 - originally called the "Osteonics Secur-Fit AD Generation II Acetabular Component System")
- Osteolock NP and Osteolock Cluster Acetabular Shells (K971854 and K933102)
- Partnership Revision Femoral Components (K972893)

Device Description

The subject Trident Acetabular Shells are characterized by the following features:

- Shell substrate: Ti6Al4V alloy.
- Surface coating: a rough layer of plasma-sprayed CP Titanium.
- Outer Shell Geometry: The subject series of Trident Acetabular Shells will include one version with the patented Dual Radius (PSL®) outer geometry and one version with a

single-radius (hemispherical) outer geometry:

- Inner Shell Geometry: An interior geometry which accommodates the predicate Trident Polyethylene Acetabular Insert through a wireless locking mechanism..
- Apical Dome Hole: This dome hole (which is not intended to receive a bone screw) is featured on all subject shell versions, and allows for attachment of the shell to implantation/removal instrumentation.
- Screw Hole Configurations: The subject shells are available in any of the following screw hole configurations:
  - Solid Back: No Screw Holes.
  - 3-Hole: Three screw holes clustered on the dome of the shell.
  - 5-Hole: Five screw holes clustered on the dome of the shell.
  - Multi-cluster: A number of screw holes (ranging from 4 to 16, depending on shell size) scattered across the dome of the shell.
  - X'tra Solid Back: Features screw holes around the periphery of the shell, but no dome screw holes.
  - X'tra Multi-cluster: Features screw holes around the periphery of the shell, and a number of screw holes (ranging from 4 to 16, depending on shell size) scattered across the dome of the shell.
- A range of outer diameter (O.D.) sizes from 40 through 80mm, in 2mm increments

In addition, the following design feature is exclusive to the Dual Radius (PSL®) versions of the subject devices:

- Circumferential Normalizations: Normalizations are distinct steps which are machined into the exterior of the shells. The circumferential normalizations on the subject shells

begin at the peripheral lip and progress approximately one third of the way up the face of the shells, decreasing gradually until the step profile is negated by the PS coating.

Intended Use:

The Trident Acetabular Shells described in this 510(k) submission are single-use devices intended for cemented or cementless fixation within the prepared acetabulum. The subject acetabular shells are intended for use with mating Trident Polyethylene Cup Inserts.

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

Statement of Technological Comparison:

Materials

The subject Trident Acetabular Shells feature the same substrate material as the predicate Trident Acetabular Shells (Ti6Al4V ELI alloy). The subject Trident Acetabular Shells feature the same plasma-sprayed Titanium coating featured on the predicate Partnership Revision Femoral Components (K972893).

Indications for Use

The subject Trident Acetabular Shells have the same indications for use as the predicate Trident Acetabular Shells.

Design

The subject Trident Acetabular Shells combine design elements that have long been employed in other commercially-available acetabular shell designs. The specific combination of design features employed in the subject Trident Acetabular Shells do not raise any new questions of safety or effectiveness.

Performance Data:

Test data characterizing the plasma-sprayed Titanium coating was provided in accordance with relevant FDA guidance documents. The shell-to-insert locking mechanism was tested to characterize fatigue strength, push-out resistance, and lever-out torque resistance. (All test data was incorporated by reference to previous 510(k)s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 4 2000

Ms. Terry Sheridan Powell
Regulatory Affairs Team Member
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K001449
Trade Name: Trident Acetabular Shells: PS
Regulatory Class: II
Product Code: LZO
Dated: May 4, 2000
Received: May 9, 2000

Dear Ms. Powell:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. 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): K001449

Device Name: Trident Acetabular Shells: PS

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dianne R. Vochner

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001449

Prescription Use X OR Over-The-Counter Use____

(Per 21 CFR 801.109) (Optional Format 1-2-96)