K013475
PG 1 OF 4

DEC 2 0 2001

510(k) Summary

Trident® Porous Titanium Acetabular Component with Peri-Apatite™ Coating

The Trident® Porous Titanium Acetabular Shells with Peri-Apatite™ Coating described in this 510(k) submission consist of single use devices which are intended for cementless fixation within the prepared acetabulum. The Trident® Porous Titanium Acetabular Shells with Peri-Apatite™ coating are intended for mating with the commercially available Trident® UHMWPE Acetabular Inserts (N_2Vac packaged and Crossfire™ styles), also single use devices.

If supplemental bone screw fixation is deemed necessary, Osteonics® 5.5mm and 6.5mm Cancellous Bone Screws (K894124, K873251) can be placed through the shells' dome screw holes without interfering with the seating of the insert.

The Trident® Porous Titanium Acetabular Shells with Peri-Apatite™ Coating are compatible with any appropriately selected, legally marketed Howmedica Osteonics hip stem/head combination.

Indications:

The indications for use of the Trident® Porous Titanium Acetabular Shell with Peri-Apatite™ Coating, in keeping with those of other legally marketed Howmedica Osteonics acetabular component systems, are as follows:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Revision of previously unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Contraindications:

As with other Howmedica Osteonics hip replacement acetabular component systems, the contraindications for the Trident® Porous Titanium Acetabular Component with Peri-Apatite™ Coating include:

- Any active or suspected latent infection in or about the hip joint.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complication in postoperative care.
- Bone stock compromised by disease, infection, or prior implantation which cannot provide adequate support and fixation of the prosthesis.
- Skeletal immaturity.
- Obesity. An overweight or obese patient can produce loads on the prosthesis which can lead to failure of the fixation of the device or to failure of the device itself.

Device Description

The Trident® Porous Titanium Acetabular Component with Peri-Apatite™ Coating, when used with the commercially available Trident® UHMWPE Acetabular Insert, is an artificial total hip replacement device which consists of an acetabular shell and a mating insert. Each insert/shell assembly is intended to resurface the acetabulum thereby providing a suitable articulating surface for a mating artificial stem/head combination.

The Trident® Porous Titanium Acetabular Component with Peri-Apatite™ Coating is manufactured from ASTM F-136 Ti6Al-4V ELI alloy, and employs a porous coating fabricated from ASTM F-67 Commercially Pure (CP) Titanium. Overlaying the porous coating is a 20 micron thick layer of Peri-Apatite™ coating.

The Trident® Porous Titanium Acetabular Shells with Peri-Apatite™ Coating are characterized by the following features:

- The outer shell has a single radius (hemispherical) geometry
- A shell substrate composed of titanium alloy (Ti6Al-4V ELI) comparable to that used in other Howmedica Osteonics acetabular components

- A titanium porous coating (CP Titanium) which meets the definition of porous coating outlined in 21 CFR 888.3358, and is comparable to that used in other Howmedica Osteonics hip and knee components
- Peri-Apatite™ coating that is used on the Vitalock® Solid Back Shell with Peri-Apatite™ coating.
- An interior geometry which allows a mating with the Trident® UHMWPE inserts through maximum conformity and a wireless locking mechanism.
- Availability with screw hole options and cluster screw holes which accept Osteonics® 5.5mm and 6.5mm Cancellous bone Screws (K873251, K894124). A dome hole which is compatible with the optional, currently marketed Osteonics® Acetabular Dome Hole Plugs (K942809). The Osteonics® 5.0mm Cancellous Screws are available for use with peripheral screw holes.
- A range of outer diameters from 40 through 82mm in 2mm increments.
- The following shell configurations will be available:
  - dome hole only, no screw holes
  - 2-3 cluster screw holes, and dome hole
  - 3-5 cluster screw holes and dome hole
  - 5 cluster screw holes with 4 inferior screw holes, and dome hole
  - 8-12 multiple dome screw holes and dome hole
  - 5-7 peripheral screw holes and dome hole

Characterization of the Peri-Apatite™ coating was presented to the extent possible using the testing outlined in the FDA document "Calcium Phosphate [Ca-P] Coating Draft Guidance for Preparation of FDA submissions for Orthopedic and Dental Endosseous Implants."

The Trident® Porous Titanium Acetabular Component with Peri-Apatite™ Coating is substantially equivalent to other legally marketed devices. These products are listed below:

1) Trident® Porous Titanium Acetabular Component – K010170
Howmedica Osteonics Corp.

2) Vitalock® Solid Back Shell with Peri-Apatite™ Coating – K971206

A discussion of the equivalent features was presented.

For further information please contact:

Margaret F. Crowe
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59 Route 17
Allendale, New Jersey 07401
(201) 934-4359

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2001

Ms. Margaret F. Crowe
Regulatory Affairs Consultant
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K013475
Trade Name: Trident™ Porous Titanium Acetabular Component w/Peri-Apatite
Regulation Number: 888.3358
Regulation Name: Prothesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented; Prosthesis, Hip, Semi-Constrained, Metal/Polymer, non-porous, Calcium
Regulatory Class: II; unclassified
Product Code: LPH; MEH
Dated: October 18, 2001
Received: October 19, 2001

Dear Ms.Crowe:

We have reviewed your Section 510(k) premarket 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) 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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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 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

K013475
page 1 of 1

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Trident® Porous Titanium Acetabular Component with Peri-Apatite™ Coating

Indications for Use:

The indications for use of the Trident® Porous Titanium Acetabular Component with Peri-Apatite™ Coating, in keeping with those of other legally marketed Howmedica Osteonics acetabular component systems, are as follows:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Revision of previously unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____
(per 21 CFR 801.109)

(Optional Format 1-2-96)

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

510(k) Number K013475