K022799
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510(k) Summary

Submission Information

Name and Address of Sponsor:	Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401
For Information contact:	Margaret F. Crowe Regulatory Affairs Consultant Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401

NOV 21 2002

Device Identification

Proprietary Name:	Trident® Screw Hole Plug and Trident® Bone Spike
Common Name:	Acetabular Screw Hole Plug Smooth Metallic Bone Fixation Fastener
Classification Name and Reference:	Trident® Screw Hole Plug: 21 CFR §888.3350 Prosthesis, Hip, Semi-constrained Cemented or 21 CFR §888.3358 Hip Joint Metal/Polymer/Metal Semi-constrained Porous Coated Uncemented Prosthesis Trident® Bone Spike 21 CFR §888.3040 Smooth or Threaded Metallic Bone Fixation Fastener
Proposed Regulatory Class:	Class II
Device Product Code:	Trident® Screw Hole Plug: OR (87) JDI OR (87) LPH Trident® Bone Spike: OR (87) HWC

The Trident® Screw Hole Plugs are optional single-use devices that are intended to occlude the unused screw holes of the Trident® Porous Titanium Acetabular Component

or the Trident® Porous Titanium Acetabular Component with Peri-Apatite™ Coating. The Trident® Screw Hole Plugs will be used either with or without bone cement depending upon the appropriate surgical application of the Trident® shell.

The Trident® Screw Hole Plugs are intended to be used in situations where the Trident® Porous Titanium Acetabular Components are intended to be used. More specifically, these Trident® Screw Holes Plugs have the following indications and contraindications:

Indications

- In cemented or cementless hip arthroplasty, when a screw hole plug is thought to be advantageous

Contraindications

- 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.

The Trident® Bone Spikes are optional single-use devices that are intended to provide supplemental fixation of the Trident® Porous Titanium Acetabular Shell or the Trident® Porous Titanium Acetabular Shell with Peri-Apatite™ Coating in the prepared acetabulum in total hip arthroplasty. These Trident® Bone Spikes are intended to be used when the above-referenced Trident® acetabular shells are used in a press fit application.

More specifically, these Trident® Bone Spikes have the following indications and contraindications:

- Trident® Bone Spikes are intended for supplemental fixation of the Trident® Porous Titanium Acetabular Shell and the Trident® Porous Titanium Acetabular Shell with Peri-Apatite Coating only.
- Trident® Bone Spikes should be assembled to the Trident® acetabular shell prior to placement of the shell into the prepared acetabulum.

The Trident® Screw Hole Plugs are small, threaded circular plugs which are intended to occlude acetabular screw holes not occupied by bone screws or the Trident® Bone Spike (subject device). The Trident® Screw Hole Plugs are fabricated from commercially pure titanium (CP Titanium). The Trident® Screw Hole Plugs incorporate a recess to accept a TORX® head screwdriver to allow the surgeon to place the desired number of plugs into the Trident® shell intraoperatively. The Trident® Screw Hole Plugs are intended to be inserted from the inside of the Trident® shell.

The Trident® Screw Hole Plugs, by occluding the shell screw holes, will help prevent intrusion of bone cement into the shell (when used in the cemented mode) or fibrous tissue (when used in a cementless mode), and potential migration of debris through open screw holes into the acetabulum.

The Trident® Bone Spike is fabricated from titanium alloy (Titanium 6 Aluminum 4 Vanadium), and is available in two lengths: 7mm and 9mm. The Trident® Bone Spike has a threaded base that is assembled to the screw hole(s) of the appropriate Trident® shell at the time of surgery. The undersurface of the base incorporates a recess to accept a TORX® screwdriver. The superior portion of the device is a spike that is intended to provide purchase into the prepared bone of the acetabulum. The surgeon has the option of using the Trident® Bone Spike in place of the Osteonics® Cancellous Bone Screws to provide supplemental fixation of the Trident® shell.

Testing was presented to support a claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2002

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

Re: K022799
Trade/Device Name: Trident® Screw Hole Plug and Trident® Bone Spike
Regulation Numbers: 21 CFR 888.3350, 21 CFR 888.3358, and 21 CFR 888.3040
Regulation Names: Hip joint metal/polymer semi-constrained cemented prosthesis; Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis; and Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: JDI, LPH, HWC
Dated: August 22, 2002
Received: August 23, 2002

Dear Ms. Crowe:

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. 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,

Miriam C. Provost

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

510(k) Number (if known): K022799

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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)

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

Miriam C. Provost

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

510(k) Number K022799