JUL 1 8 2001

K012026 p1/2

Special 510(k) Summary - Device Modification
for the Trident® All Poly Cup

Proprietary Name:	Trident® All Poly Cup
Common Name:	All Polyethylene Acetabular Cup
Classification Name and Reference:	21 CFR §888.3350 Hip joint metal/polymer semi-constrained cemented prosthesis
Proposed Regulatory Class:	II
Device Product Code:	87 JDI Prosthesis, hip, semi-constrained, metal/polymer, cemented
For Information contact:	Jennifer A. Daudelin, Regulatory Affairs Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677 (201) 934-4354 Fax: (201) 760-8435 Email: jdaudelin@howost.com

This Special 510(k) submission is intended to address a material modification to the radiographic marker of the Trident® All Poly Cup. The predicate Trident® All Poly Cup was found substantially equivalent via the 510(k) process in 510(k)s #K001956 and #K010310. The predicate Tantalum Bead Radiographic Marker was found substantially equivalent via 510(k) #K010348. The design, manufacturing methods, intended use, packaging and sterilization of the subject device are identical to those of predicate Trident® All Poly Cup .

The subject Trident® All Poly Cups are polyethylene acetabular components that are intended to replace the bearing portion of the acetabulum in primary or revision total hip arthroplasty. The subject device is designed to be cemented into the acetabulum. These acetabular cups are intended to be used with any Howmedica Osteonics' femoral head.

The subject Trident® All Poly Cup is available in Crossfire™ UHMWPE with a tantalum bead radiographic marker. The predicate device is also manufactured from Crossfire™ UHMWPE;

however, the radiographic marker is a cobalt chromium alloy bead. The Crossfire™ UHMWPE material conforms to ASTM F-648. The radiographic marker of the subject device complies with ASTM standard F-560 while the radiographic marker for the predicate device conforms to ASTM F-1377.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 8 2001

Ms. Jennifer A. Daudelin
Regulatory Affairs
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K012026
Trade/Device Name: Trident® All-Poly Cup
Regulation Number: 888.3350
Regulatory Class: II
Product Code: JDI
Dated: June 27, 2001
Received: June 28, 2001

Dear Ms. Daudelin:

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 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). 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 requirements, 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" (21CFR 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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/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

Indications for Use

510(k) Number (if known): K012026

Device Name: Trident® All Poly Cup

Indications for Use:

The Trident™ All Poly Cup is a polyethylene acetabular component that is intended to replace the bearing portion of the acetabulum in primary or revision total hip arthroplasty. This cup is designed to be cemented into the acetabulum. These acetabular cups are intended to be used with any Howmedica Osteonics' femoral head.

(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 K012026