MAR 2 0 2001

K01 0310

Special 510(k) Summary - Device Modification
Summary of Safety and Effectiveness 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 Trident™ All Poly Cup. The design, manufacturing methods, intended use, packaging and sterilization of the subject device are identical to those of predicate device. The predicate device was found substantially equivalent via the 510(k) process in 510(k) #K001956. The predicate and subject devices are polyethylene acetabular components that are intended to replace the bearing portion of the acetabulum in primary or revision total hip arthroplasty. Like the predicate, this cup is designed to be cemented into the acetabulum.

The subject Trident™ All Poly Cup is available in Crossfire™ UHMWPE in outer diameters of 40mm to 50mm in two millimeter increments and inner diameters of 22mm, 26mm, 28mm, and 32mm. The predicate device is manufactured from standard Ultra High Molecular Weight Polyethylene while the subject devices are manufactured from Crossfire™ Ultra High Molecular Weight Polyethylene. Both materials conform to ASTM F-648.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2001

Ms. Elizabeth A. Staub
Vice President
Regulatory Affairs, Quality Assurance and Clinical Research
Stryker Howmedica Osteonics
59 Route 17
Allendale, Pennsylvania 07401-1677

Re: K010310
Trade Name: Trident™ All Poly Cup
Regulatory Class: II
Product Codes: JDI
Dated: March 8, 2001
Received: March 9, 2001

Dear Ms. Staub:

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,

for Mark N Melkerson

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

K010310

Indications for Use

510(k) Number (if known): K010310

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.

for Mark N Milkerson

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

510(k) Number K010310

(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)