K021911

P. 1/2

JUL - 2 2002

Special 510(k) Summary

Line Extension to the Trident® Polyethylene Acetabular System - Trident® Crossfire® Polyethylene Liners

Proprietary Name:	Trident® Crossfire® Polyethylene Liners
Common Name:	Artificial Hip Components
Classification Name and Reference:	Hip joint, metal/polymer/metal semi-constrained porous-coated uncemented prosthesis 21 CFR §888.3358
Proposed Regulatory Class:	Class II
Device Product Code:	87 LPH
Predicate Proprietary Name(s):	Osteonics® Secur-Fit™ AD Generation II Acetabular Component System; Line Extension, Osteonics® Trident® Polyethylene Inserts; and Line Extension, Trident® Elevated Rim Liners
Predicate Regulatory Class:	Class II
Predicate Product Code(s):	87 LPH and LZO
For Information Contact:	Debra Bing Howmedica Osteonics Corp. 59 Route 17 Allendale, New Jersey 07401-1677 Phone: (201) 831-5413 Fax: (201) 831-6038

Description/Technological Comparison

The existing Trident® Polyethylene Acetabular System features acetabular liners in neutral, hooded, eccentric and elevated rim versions. The subject Trident® Crossfire® Polyethylene Liners are an addition to the existing liners (standard and eccentric versions). The subject liners will be offered in fourteen new sizes which include the addition of a 36mm size eccentric liner in

both 0° and 10° versions and 26mm, 28mm, 32mm and 36mm size standard liners in both 0° and 10° versions in the same polyethylene thicknesses as the Trident® Elevated Rim Liners. The subject liners, like the predicate liners, are manufactured using Crossfire® polyethylene.

Intended Use

The subject acetabular liners are single-use devices intended for use in total hip replacement. They are intended for mechanical assembly to predicate Trident® series acetabular shells. (The predicate Trident® series shells are intended for cementless fixation.)

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 failed 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.

Testing Summary

Engineering analysis was employed to ensure that the risk of cam-out for the subject device is less than the risk associated with predicate devices. Hip wear simulator testing of a similar cup liner was used to demonstrate the comparable safety and effectiveness of the new liner sizes in the subject series to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2002

Mr. William J. Cymbaluk
Vice President
Quality Assurance, Regulatory Affairs and Clinical Research
Stryker Howmedica Osteonics Corporation
59 Route 17 South
Allendale, NJ 07401

Re: K021911
Trade Name: Trident® Crossfire® Polyethylene Liners
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH
Dated: June 7, 2002
Received: June 11, 2002

Dear Mr. Cymbaluk:

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

510(k) Number (if known): K021911

Device Name: Line Extension to the Trident® Polyethylene Acetabular System-Trident® Crossfire® Polyethylene Liners

The subject acetabular liners are single-use devices intended for use in total hip replacement. They are intended for mechanical assembly to predicate Trident® series acetabular shells. (The predicate Trident® series shells are intended for cementless fixation.)

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 failed 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.

(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)
(Optional Format 1-2-96)

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

510(k) Number K021911