SEP 2 2 1998

K974685

510(k) Summary
Osteonics® Polyethylene Acetabular Components

Sponsor of the 510(k) Submission:	Osteonics Corporation 59 Route 17 Allendale, NJ 07401-1677 201-825-4900
Contact Person:	Donna S. Wilson Regulatory Affairs Specialist
Date 510(k) Summary Prepared:	August 27, 1998
Device Proprietary Name:	Osteonics® Polyethylene Acetabular Components
Device Common Name:	Polyethylene Acetabular Inserts
Device Classification Reference:	21 CFR §888.3350, §888.3358

Predicate Device Identification

The subject Osteonics® (Crossfire™) Polyethylene Acetabular Components fabricated from the subject crosslinked polyethylene are substantially equivalent to their identical predicate counterparts fabricated from the current (standard) polyethylene utilized at Osteonics Corp.

Device Description

Osteonics® Crossfire™ Polyethylene Acetabular Components consist of the following devices: Osteonics® Omnifit® 10° Cup Insert - Series II (2041C); Osteonics® Omnifit® 20° Cup Insert - Series II (2042C); Osteonics® Omnifit® 0° Cup Insert - Series II (2043C); Osteonics® Omnifit® Eccentric 10° Cup Insert (S2301C); Osteonics® Omnifit® Eccentric 20° Cup Insert (S2302C).

Intended Use

Osteonics® Crossfire™ Polyethylene Acetabular Components are single use components, intended for use in conjunction with an associated Osteonics® metal acetabular shell, femoral bearing, and femoral hip stem, as part of a cemented or cementless total hip arthroplasty. Indications for use, in keeping with those of other commercially available Class II total hip devices, are as follows: painful, disabling joint disease of the hip resulting from degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis; revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure; clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results; and, where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Wear Claims

The Osteonics® Crossfire™ Polyethylene Acetabular Inserts, 2041C-2850, show a 90% reduction in gravimetric wear rate versus the same acetabular inserts fabricated from standard polyethylene, 2041-2850. These inserts mate with a 50mm acetabular shell, have a 10° elevated rim, a 28mm inner diameter, and a 9.4mm bearing thickness. Testing was performed under multiaxial hip joint simulation for 5 million cycles, using a 28mm CoCr articulating counterface and a bovine calf serum lubricant. The results of *in vitro* hip wear simulator tests have not been shown to quantitatively predict clinical wear performance.

The Osteonics® Crossfire™ Polyethylene Acetabular Inserts, 2041C-2850, show an 88% reduction in gravimetric wear rate versus the same acetabular inserts fabricated from standard polyethylene, 2041-2850, when evaluated following an accelerated aging cycle. These inserts mate with a 50mm acetabular shell, have a 10° elevated rim, a 28mm inner diameter, a 9.4mm bearing thickness, and were aged under 80°C in air for 14 days. Testing was performed under multiaxial hip joint simulation for 5 million cycles, using a 28mm CoCr articulating counterface and a bovine calf serum lubricant. The results of *in vitro* hip wear simulator tests have not been shown to quantitatively predict clinical wear performance.

The Osteonics® Crossfire™ Polyethylene Acetabular Inserts, 2041C-2850, show an 78% reduction in gravimetric wear rate versus the same acetabular inserts fabricated from standard polyethylene, 2041-2850, when evaluated under abrasive wear conditions. These inserts mate with a 50mm acetabular shell, have a 10° elevated rim, a 28mm inner diameter, and a 9.4mm bearing thickness. Testing was performed under multiaxial hip joint simulation for 5 million cycles, using a 28mm CoCr articulating counterface, a bovine calf serum lubricant, and an abrasive media of bone cement particulate. The results of *in vitro* hip wear simulator tests have not been shown to quantitatively predict clinical wear performance.

Statement of Technological Comparison

The intended use, indications, contraindications, and design specifications of the subject components remain identical to their predicate component counterparts. The raw material being utilized in the manufacture of both the subject and predicate devices remains as ultra-high molecular weight polyethylene (UHMWPE) per ASTM F-648. The modifications to the manufacturing process of this polyethylene will be introduced in order to create a higher crosslinked polyethylene. The safety and effectiveness of this crosslinked polyethylene in acetabular applications, as well as the proposed wear claims, are adequately supported by the substantial equivalence information, materials data and testing results provided within this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 22 1998

Ms. Donna S. Wilson
Regulatory Affairs Specialist
Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K974685/S1
Osteonics® Crossfire™ Polyethylene Acetabular Components
Regulatory Class: II
Product Code: JDI, LWJ and LPH
Dated: July 2, 1998
Received: July 7, 1998

Dear Ms. Wilson:

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 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 requirement, 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" (21 CFR 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 at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K974685

Device Name: Osteonics® Polyethylene Acetabular Components

Indications For Use:

Osteonics® Crossfire™ Polyethylene Acetabular Components are single use components, intended for use in conjunction with an associated Osteonics® metal acetabular shell, femoral bearing, and femoral hip stem, as part of a cemented or cementless total hip arthroplasty. Indications for use, in keeping with those of other commercially available Class II total hip devices, are as follows:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful 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 inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Osteonics® (Crossfire™) Polyethylene Acetabular Components consist of the following devices:

- Osteonics® Omnifit® 10° Cup Insert - Series II (2041C)
- Osteonics® Omnifit® 20° Cup Insert - Series II (2042C)
- Osteonics® Omnifit® 0° Cup Insert - Series II (2043C)
- Osteonics® Omnifit® Eccentric 10° Cup Insert (S2301C)
- Osteonics® Omnifit® Eccentric 20° Cup Insert (S2302C)

(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 Devices
510(k) Number K974685

Wear Claims:

The Osteonics® Crossfire™ Polyethylene Acetabular Inserts, 2041C-2850, show a 90% reduction in gravimetric wear rate versus the same acetabular inserts fabricated from standard polyethylene, 2041-2850. These inserts mate with a 50mm acetabular shell, have a 10° elevated rim, a 28mm inner diameter, and a 9.4mm bearing thickness. Testing was performed under multiaxial hip joint simulation for 5 million cycles, using a 28mm CoCr articulating counterface and a bovine calf serum lubricant. The results of *in vitro* hip wear simulator tests have not been shown to quantitatively predict clinical wear performance.

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Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
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