K993352

NOV 19 1999

510(k) Summary

Additional Crossfire™ Acetabular Components

Submission Information

Name and Address of the Sponsor:	Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Terry Sheridan Powell
Date of Summary Preparation:	November 19, 1999

Device Identification

Proprietary Name:	Crossfire™ System 12® Acetabular Inserts
Common Name:	Artificial Total Hip Replacement Component (Acetabular Inserts)
Classification Name and Reference:	888.3358: Prosthesis, hip, semi-constrained, metal-polymer, porous, uncemented

Predicate Device Identification

- Osteonics Polyethylene Acetabular Inserts, fabricated from crosslinked polyethylene called "Crossfire", were determined Substantially Equivalent via 510(k) #K974685 on 12/16/97 (sponsor: Osteonics Corp.).

- Howmedica System 12® Acetabular Inserts (non-Crossfire) were determined Substantially Equivalent as follows:
  - via 510(k) #K903362. These were room air irradiated versions, previously called Osteolock inserts (sponsor: Howmedica Inc..).
  - via 510(k) #K951114. These were room air irradiated versions, specifically for the additional P1 26mm size.
  - via 510(k) #K951115. These were room air irradiated versions, specifically for the additional 22mm sizes.
  - via 510(k) #K934060. These were Duration® Stabilized versions.
  - via 510(k) #K963612. This submission allowed additional wear claims for the Duration® Stabilized versions.

Device Description

The subject Crossfire™System 12® Acetabular Inserts are the same as the predicate non-Crossfire™System 12® Acetabular Inserts, except that the subject devices are fabricated from polyethylene that has been crosslinked via the procedure described in, and found Substantially Equivalent in, 510(k) #K974685.

Intended Use:

The subject devices are single use components, intended for use in conjunction with associated acetabular shells, femoral bearings, and femoral hip stems as part of a cemented or cementless total hip replacement procedure. Indications for use, in keeping with those of other commercially available Class II total hip devices, are as follows:

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis,
- rheumatoid arthritis,
- correction of functional deformity,
- revision procedures where other treatments or devices have failed, and
- treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Statement of Technological Comparison:

Materials

The subject and predicate Crossfire™ System 12® Acctabular Inserts are manufactured from UHMWPE per ASTM-F648. The UHMWPE material to be used for the subject System 12® Acetabular Inserts will be crosslinked in exactly the same manner used for the acetabular inserts determined Substantially Equivalent via K974685.

Indications for Use

The indications for use of the subject and predicate System 12® Acetabular Inserts are identical.

Design

The subject (Crossfire) and predicate (non-Crossfire) System 12® Acetabular Inserts are identical in design. Additional testing has been performed on Crossfire™ versions of the System 12® Acetabular Inserts to validate that these inserts are not adversely affected, with regard to locking strength or fatigue strength, as a result of the Crossfire™ process.

Performance Data:

Crossfire polyethylene has been well characterized previously under 510(k) #K974685. Testing of the subject acetabular inserts, therefore, focused on the structural aspects of System 12 inserts assembled within Howmedica-design (e.g., Osteolock) acetabular shells.

The smallest insert size (P1) was assembled within metal backings and fatigue loaded. After 10^7 cycles, three inserts were axially distracted (pushed-out) and two were carefully removed by sectioning their metal shells. All inserts were inspected for signs of structural compromise with no gross evidence of impending catastrophic failure. Other surface features, e.g. screw hole impressions, were consistent with those observed in an earlier study used to originally qualify Osteonics-design Crossfire inserts. Axial distraction test results demonstrated sufficient locking strength pre-and post- fatigue testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 1999

Ms. Elizabeth Staub
Vice President, Quality Assurance/Regulatory
Affairs/Clinical Research
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K993352
Trade Name: Additional Crossfire™ Acetabular Components
Regulatory Class: II
Product Codes: LPH and JDI
Dated: November 4, 1999
Received: November 8, 1999

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 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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993352

Device Name: Additional Crossfire™ Acetabular Components

Indications For Use:

The subject devices are single use components, intended for use in conjunction with associated acetabular shells, femoral bearings, and femoral hip stems as part of a cemented or cementless total hip replacement procedure. Indications for use, in keeping with those of other commercially available Class II total hip devices, are as follows:

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis,
- rheumatoid arthritis,
- correction of functional deformity,
- revision procedures where other treatments or devices have failed, and
- treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

The additional Crossfire™ Acetabular Inserts include the following devices:

- System 12® Acetabular Inserts

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993352

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Wear Claims:

The Howmedica 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 Howmedica 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 Howmedica Osteonics Crossfire Polyethylene Acetabular Inserts, 2041C-2850, show a 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.