510(k) Summary: Omnifit® HFx Hip Stem Series

Proprietary Name:	Omnifit® HFx Hip Stem Series
Common Name:	Femoral Hip Stems
Classification Name and Reference:	Hip joint, metal/polymer semi-constrained, cemented prosthesis 21 CFR §888.3350 Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis 21 CFR §888.3360
Proposed Regulatory Class:	Class II
Device Product Code:	87 – JDI: Prosthesis, hip, semi-constrained, cemented 87 – LWJ: Prosthesis, hip, semi-constrained, metal/polymer, uncemented
Predicate Proprietary Name(s):	Osteonics ODC/ODC Plus Hip Stems, Omnifit X (Eon) Hip Stems
Predicate Regulatory Class:	Class II
Predicate Product Code(s):	87 JDI, KWL
Submitted By:	Howmedica Osteonics Corp. 59 Route 17 Allendale, New Jersey 07401-1677 (201) 825-4900
Contact Information:	Debra Bing Phone: (201) 831-5413 Fax: (201) 831-6038
Date Summary Prepared:	July 23, 2003

Description/Technological Comparison

The subject and predicate hip stems are both hip fracture stems intended for cementless or cemented use. The subject devices and the predicate 6076 series hip stems (K954598) are forged from ASTM F-799 cobalt chromium alloy.

Intended Use

The subject devices are intended for single use only, and may be used with or without bone cement. The subject devices may be used with an Howmedica Osteonics Endo Head and Neck Extension for hemi-hip arthroplasty, a UHR® Universal Head for bipolar hip replacement, or a Howmedica Osteonics C-Taper cobalt chromium head and Howmedica Osteonics acetabular component for conventional total hip arthroplasty.

Indications:

For use as a bipolar hip replacement

- Femoral head/neck fractures or non-union,
- Aseptic necrosis of the femoral head,
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion,
- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum,
- Salvage of failed total hip arthroplasty
- Femoral Neck Fractures

For use as a total hip replacement

- Painful, disabling joint disease 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,
- Clinical circumstances that require an altered femoral resection level due to proximal fracture, bone loss, or calcar lysis.

Testing Summary

Finite Element Analysis was used to evaluate the strength of the neck and body regions of the hip stems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2003

Ms. Debra Bing
Regulatory Affairs Manager
Howmedica Osteonics Corp.
59 Route 17
Allendale, New Jersey 07401

Re: K031744
Trade/Device Name: Omnifit® HFx Hip Stem Series
Regulation Number: 21 CFR 888.3350 and 21 CFR 888.3360
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis and Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Regulatory Class: II
Product Code: JDI, LWJ, and KWL
Dated: June 4, 2003
Received: June 5, 2003

Dear Ms. Bing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

Miriam C. Provost

for Celia 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): _____

Device Name: Omnifit® HFx Hip Stem Series

The subject devices are intended for single use only, and may be used with or without bone cement. The subject devices may be used with an Howmedica Osteonics Endo Head and Neck Extension for hemi-hip arthroplasty, a UHR® Universal Head for bipolar hip replacement, or a Howmedica Osteonics C-Taper cobalt chromium head and Howmedica Osteonics acetabular component for conventional total hip arthroplasty.

Indications:

For use as a bipolar hip replacement

- Femoral head/neck fractures or non-union,
- Aseptic necrosis of the femoral head,
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion,
- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum,
- Salvage of failed total hip arthroplasty
- Femoral Neck Fractures

For use as a total hip replacement

- Painful, disabling joint disease 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.
- Clinical circumstances that require an altered femoral resection level due to proximal fracture, bone loss, or calcar lysis.

(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)

Miriam C. Provost

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

510(k) Number K031744