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APR 2 6 2002

Special 510(k) Summary – SUPER EON PLUS FEMORAL STEMS

	SUBJECT DEVICE	PREDICATE DEVICE
Proprietary Name:	Super EON Plus Femoral Stems	Omnifit EON Femoral Stems
Common Name:	Artificial Hip Component	Artificial Hip Component
Classification Name and Reference:	21 CFR §888.3350 Hip Joint Metal/ Polymer Semi-constrained Cemented Prosthesis	21 CFR §888.3350 Hip Joint Metal/ Polymer Semi-constrained Cemented Prosthesis
Proposed Regulatory Class:	II	II
Device Product Code:	(87) JDI	(87) JDI
For Information contact:	Jennifer A. Daudelin, Regulatory Affairs Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677 (201) 831-5379 Fax: (201) 760-8435 Email: jdaudelin@howost.com	

Device Description

This Special 510(k) submission is intended to address a design modification to the Omnifit EON Femoral Stems. This modification will create the new subject device, hereby referred to as the Super EON Plus femoral stems to expand the product line. The intended use, manufacturing methods, materials, packaging and sterilization of the subject device are identical to those of predicate devices. The subject device is fabricated from forged cobalt chromium alloy conforming to ASTM F 799. The Super EON Plus femoral stems are available in 127 degree and 132 degree neck angles and range in size from size #4 through size #10.

Predicate Device

The predicate Omnifit EON femoral stems were found substantially equivalent via the 510(k) process in K983226.

Statement of Technological Comparison

Fatigue testing of the subject Super EON Plus femoral stems demonstrated that the body and neck strength are comparable to the body and neck strength of the predicate Omnifit EON Femoral Stems.

Intended Use

Like the predicate devices, the subject devices are intended for primary and revision total or hemi-hip arthroplasty. These devices are intended for use in cemented applications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 6 2002

Ms. Jennifer A. Daudelin
Regulatory Affairs Associate
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K020989
Trade Name: Super EON Plus Femoral Stem
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip Joint Metal / Polymer / Semi-Constrained / Cemented Prosthesis
Regulatory Class: II
Product Code: JDI
Dated: March 26, 2002
Received: March 27, 2002

Dear Ms. Daudelin:

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,

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

Indications for Use

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510(k) Number (if known): K020989

Device Name: Super EON Plus Femoral Stems

Indications for Use:

Indications for use as a Bipolar or Hemi-Hip Replacement:

- Femoral head/neck fractures or non-unions
- 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.

Indications for use as part of a Total Hip Replacement include:

- 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.

Mark N Milham

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

510(k) Number K020989

(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)