Special 510(k) Summary - Device Modification
Summary of Safety and Effectiveness for the
Howmedica Osteonics Femoral Heads

Proprietary Name: Howmedica Osteonics Femoral Heads

Common Name: Modular Femoral Head

Classification Name and Reference: Hip joint metal/polymer semi-constrained cemented prosthesis, 21 CFR §888.3350

Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, 21 CFR §888.3358

Proposed Regulatory Class: Class II

Device Product Code: OR (87) JDI
OR (87) LWJ

For Information contact: Nancy J. Rieder
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This Special 510(k) submission is intended to address a design modification to the V40™ and P.C.A.® femoral heads previously manufactured by Howmedica Inc. These femoral heads are available in a range of outer diameter sizes and offsets, and were intended to mate with femoral stems with a 5° 40' taper angle, and 2° 52' taper angle, respectively. These femoral heads were also intended to mate with acetabular components (bipolar and unipolar components, as well as one and two piece acetabular components) manufactured by Howmedica Inc. Since the merger of Howmedica Inc. with Osteonics Corp. (a wholly owned subsidiary of Stryker Corp.), it is desired that these femoral heads should be compatible with acetabular components (bipolar, unipolar, and one and two piece acetabular cups) previously manufactured by Osteonics Corp. In order for this to be accomplished, there must be a design modification made to the femoral heads: a small chamfer must be added to the base of the femoral head to assure that there will not be impingement on the Osteonics bipolar component.

It is also desired that femoral heads manufactured by Osteonics be compatible with Howmedica acetabular components. No design change is required to allow Osteonics femoral heads to mate with Howmedica acetabular cups, however, a labeling change will be made to address the compatibility of these components.

The modified components, the V40™ and P.C.A.® femoral heads, are substantially equivalent to the predicate devices which were cleared for marketing via the 510k) process. The V40™ and P.C.A.® femoral heads are manufactured from wrought cobalt-chromium-molybdenum (Vitallium®) alloy which conforms to ASTM F-1537. The intended use of the subject V40™ and P.C.A.® femoral heads is identical to that of the predicate V40™ and P.C.A.® femoral heads.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 1999

Ms. Nancy J. Rieder
Rutherford Regulatory Affairs
Howmedica Osteonics Corporation
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

Re: K993601
Trade Name: Howmedica Osteonics Femoral Heads
Regulatory Class: II
Product Codes: JDI, LWJ, and KWY
Dated: October 22, 1999
Received: October 25, 1999

Dear Ms. Rieder:

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,

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): K993601

Device Name: Howmedica Osteonics Femoral Heads

Indications for Use:

These devices are modular components of a total hip system. These femoral heads are intended for use with femoral stems and acetabular components in primary or revision total hip arthroplasty.

(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 Devices
510(k) Number K993601