

OCT 8 1999

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**Special 510(k) - Device Modification
Summary of Safety and Effectiveness for the
Howmedica Osteonics® Restoration™ HA Hip Stems**

Submission Information

**Name and Address of the Sponsor
of the 510(k) Submission:**

Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401-1677

Contact Person:

Mary-Catherine Dillon
Regulatory Affairs Specialist

Date of Summary Preparation:

September 7, 1999

Device Identification

Proprietary Name:

Howmedica Osteonics® Restoration™ HA
Hip Stem

Common Name:

Hip Prosthesis

Classification Name and Reference:

Hip Joint, Metal/Ceramic/Polymer, Semi-
Constrained, Cemented or Non-Porous
Uncemented Prosthesis
21 CFR §888.3353

Predicate Device Identification

The modified features of the Howmedica Osteonics® Restoration™ HA Hip Stems are substantially equivalent to features of the following Osteonics predicate devices, which have been cleared for marketing via the 510(k) process:

- Osteonics® Restoration™ HA Hip Stems

Device Description

The Osteonics® Restoration™ HA Hip Stems are currently marketed devices that are being modified (and titled Howmedica Osteonics® Restoration™ HA Hip Stems). The modification involves introducing two new stem sizes, size 5 and size 6, each with two distal diameters, 9mm and 11mm for the size 5, and 10mm and 12mm for the size 6. Additionally, the stem length will be reduced by 10mm (from 155mm to 145mm) for 6512-xxxx and by 30mm (from 205mm to 175mm) for 6513-

xxxx. All other aspects of the Restoration™ HA Hip Stems will remain unchanged.

Intended Use:

The Restoration™ HA Hip Stems are single use components. They are intended for cementless fixation within the prepared femoral canals of patients requiring hip arthroplasty. The modified and predicate hip stems are intended to be used in conjunction with any commercially available Howmedica Osteonics C-Taper femoral bearing head. For use as a total hip replacement, the modified and predicate stems may be used in conjunction with any legally marketed Howmedica Osteonics acetabular component. The Restoration™ HA Hip Stems are manufactured from titanium alloy (ASTM F-620-97). The indications for the Restoration™ HA Hip Stems include the following:

For Use as a Bipolar 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.

Other Considerations:

- 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.

For Use as a Total Hip Replacement:

- 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.

Additional Indication for Howmedica Osteonics Head/Neck Stems:

- Clinical circumstances which require an altered femoral resection level due to a proximal fracture, bone loss, or calcar lysis.

Performance Data:

Mechanical testing has been performed to demonstrate the substantial equivalence of this Howmedica Osteonics stem design to predicate stem designs in terms of its fatigue strength.

Statement of Technological Comparison:

All features of the Restoration™ HA Hip Stems will remain the same with the following exceptions:

1) The stem size will be decreased to size 5 (with 9mm and 11 mm distal diameters) and size 6 (with 10mm and 12mm distal diameters) and 2) The overall stem length will be reduced by 10mm (from 155mm to 145mm) for 6512-xxxx and 30mm (from 205mm to 175mm) for 6513-xxxx.



OCT 8 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Mary-Catherine Dillon
Regulatory Affairs Specialist
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K993077
Trade Name: Howmedica Osteonics® Restoration™ HA Stems
Regulatory Class: II
Product Code: MEH
Dated: September 7, 1999
Received: September 14, 1999

Dear Ms. Dillon:

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.

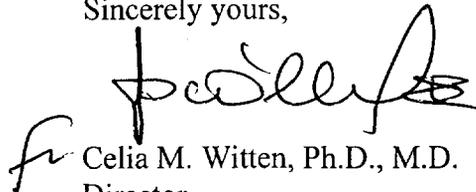
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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) 594-4595. 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,



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): K993077

Device Name: Howmedica Osteonics® Restoration™ HA Stems

Indications For Use:

The indications for the use of the Howmedica Osteonics® Restoration™ HA Stems, in keeping with those of other legally marketed Howmedica Osteonics femoral components, are as follows:

For Use as a Bipolar 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.

Other Considerations:

- 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.

For Use as a Total Hip Replacement:

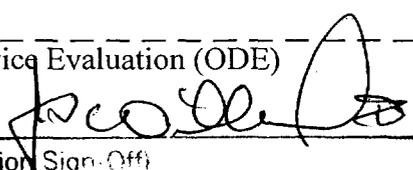
- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

Additional Indication for Howmedica Osteonics Head/Neck Stems:

- Clinical circumstances which require an altered femoral resection level due to a 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)


 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K993077

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)