

JUL 23 1999

K980070

Osteonics HA-Coated Devices

510(k) Summary

**510(k) Premarket Notification  
Summary of Safety and Effectiveness  
for the  
Osteonics® HA-AD Coated Devices**

**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:**

Marybeth Naughton  
Regulatory Affairs Team Member

**Date of Summary Preparation:**

July 14, 1999

**Device Identification**

**Proprietary Name:**

Osteonics HA-AD Coated Devices

**Common Name:**

Artificial hip implant components

**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 subject Osteonics HA-AD Coated devices have already been determined substantially equivalent. This 510(k) involves only the addition of specific claims related to the performance of Osteonics' HA-AD coating.

**Device Description**

The devices which are the subject of this 510(k) are commercially-available Osteonics hip

**Osteonics HA-Coated Devices****510(k) Summary**

acetabular and hip femoral components featuring Osteonics' HA-AD coating.

**Intended Use**

All devices covered by this submission are single-use, acetabular or femoral hip implant devices intended for cementless applications.

**Indications for Osteonics® HA-AD Acetabular Components**

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous failed femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

**Indications for Osteonics® HA-AD Femoral Components****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.
- 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.

**Statement of Technological Comparison**

Each device which is subject to this 510(k) has already been determined Substantially Equivalent for its labeled indications. This 510(k) involves no change in design, intended use, indications for use, or materials. The sole purpose of this 510(k) is to obtain FDA's permission to discuss specific performance attributes of Osteonics' HA-AD Coating.

**Osteonics HA-Coated Devices****510(k) Summary****Performance Data**

Reports of published literature were presented within this 510(k) to demonstrate additional performance claims for Howmedica Osteonics' HA-AD Coatings. The following points relevant to the performance of Osteonics' HA-AD Coating have been demonstrated in the referenced literature reports:

Howmedica Osteonics' HA/AD (Hydroxylapatite/Arc-Deposited) Coating increases bone apposition (Ref. 1), linear bone contact (Ref. 3) and the degree of bone penetration into implantable chambers (Ref. 2) as compared to AD coated samples as demonstrated in the animal models\*. The above increased bony response for HA/AD coated implants may be evidenced as early as 6 weeks after implantation.

\*Animal data may not predict human clinical results because of inter-species differences.

**References:**

- ▶ Agins HJ, Bauer TW, Kudrna JC, Cannestra V, Ming J. Cortical Remodeling and Bone Apposition on a Textured Canine Hip Implant with and without Hydroxylapatite. *Trans, AAOS*, February 1997.
- ▶ Hawkins M, Ricci JL. Arc Deposited CP Titanium with and without Hydroxyapatite Coating. Preclinical Evaluation Using the Canine Implantable Chamber Model. *Hydroxylapatite Coated Hip and Knee Arthroplasty* ed: JA Epinette and RGT Geesink, Pp 90-95, Expansion Scientifique Francaise, 1995.
- ▶ Walenciak MT, Zimmerman MC, Harten RD, Ricci JL, Stamer DT. Biomechanical and Histological Analysis of an HA-Coated, Arc Deposited CPTi Canine Hip Prosthesis. *J. Biomed. Mater. Res.* 31 (4):465-474, 1996.



JUL 23 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Marybeth Naughton  
Regulatory Affairs Team Member  
Howmedica Osteonics Corp.  
59 Route 17  
Allendale, New Jersey 07401-1677

Re: K980070  
Trade Name: Osteonics HA-Coated Devices  
Regulatory Class: II  
Product Code: MEH  
Dated: July 2, 1999  
Received: July 6, 1999

Dear Ms. Naughton:

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.

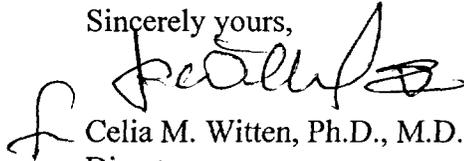
A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General Regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (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.

Page 2 – Ms. Marybeth Naughton

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. Furthermore, for questions regarding 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and a long horizontal stroke at the end.

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): K980070

Device Name: Osteonics® HA-AD Coated Devices

**Indications For Use:**

The Osteonics® HA-AD Coated Devices are single-use, acetabular or femoral hip implant devices intended for cementless applications. The following indications for use are consistent with previous submissions for these acetabular and femoral components intended for cementless application.

**Indications for Osteonics® HA-AD Acetabular Components**

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous failed femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

**Indications for Osteonics® HA-AD Femoral Components**

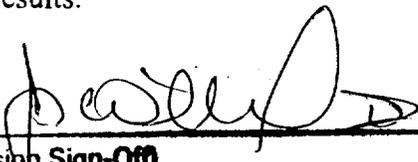
**For use as a Bipolar Hip Replacement :**

- 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.
- 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.

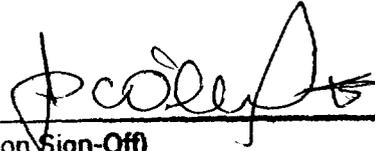
Prescription Use X  
(Per 21 CFR 801.109)

  
 (Division Sign-Off)  
 Division of **General Restorative Devices**  
 510(k) Number K980070

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K980070

Prescription Use Y OR Over-The-Counter Use No (per 21 CFR 801.109 (Optional Format 1-2-96))