

MAR 16 1998

**510(k) Summary  
Osteo Austin Moore Endoprosthesis System**

**Submission Information**

**Name and Address of the Sponsor:** Osteonics Corporation  
59 Route 17  
Allendale, NJ 07401-1677

**Name and Address of the Manufacturer:** Osteo AG  
Bohnackerweg 1  
CH-2545 Selzach  
Switzerland

**Contact Person:** Terry Sheridan  
Regulatory Affairs Specialist

**Date of Summary Preparation:** December 22, 1997

**Device Identification**

**Proprietary Name:** Osteo Austin Moore Endoprosthesis System

**Common Name:** Artificial hemi-hip stem

**Classification Name and Reference:** 888.3360:Hip joint femoral(hemi-hip) metallic cemented or uncemented prosthesis

**Predicate Device Identification**

Howmedica Austin Moore Endoprosthesis, Howmedica Inc.

**Device Description**

The Osteo Austin Moore Endoprosthesis System comes in a range of sizes to address variations in patient anatomy, and is intended for hemi-hip replacement procedures. It is intended to articulate with the natural acetabulum, and is intended for cemented use only.

**Intended Use:**

The Osteo Austin Moore Endoprosthesis System is a one-piece, hemi-hip replacement component. It is intended for cemented use only.

**Indications**

- Femoral head/neck fractures
- Aseptic necrosis of the femoral head
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement.

**Statement of Technological Comparison:**

The substantial equivalence of the Osteo Austin Moore Endoprosthesis System is supported by a comparison of the subject device to the above-cited predicate devices with regard to intended use, materials, and design.

*Intended Use*

Both the subject devices and the predicate devices are intended for hemi-hip replacement for the specified indications, and are intended for cemented use.

*Materials*

The subject devices and predicate devices are both cast from cobalt chromium alloy.

*Design*

The subject and predicate devices both feature the classic Austin-Moore design. This design includes a fixed-head for articulation with the acetabulum, and fenestrations for cement interdigitation.

**Performance Data:**

The Osteo Austin Moore Endoprosthesis System has been tested to ensure that the subject devices can withstand anticipated in-vivo loading conditions. All specimens successfully endured 10 million cycles of physiologically relevant loading.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 16 1998

Robert A. Koch, J.D.  
Director, Regulatory Affairs  
Osteonics Corporation  
59 Route 17  
Allendale, New Jersey 07401-1677

Re: K974807  
Trade Name: Osteo Austin Moore Endoprosthesis System  
Regulatory Class: II  
Product Code: KWL  
Dated: December 22, 1997  
Received: December 23, 1997

Dear Mr. Koch:

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.

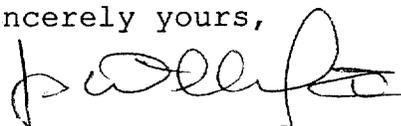
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Robert A. Koch, J.D.

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,



f 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): K 974807

Device Name: Osteo Austin Moore Endoprosthesis System

Indications For Use:

The subject devices are intended for hemi-hip replacement. They are intended for cemented use only.

*Indications*

- Femoral head/neck fractures
- Aseptic necrosis of the femoral head
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  (Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

  
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(Divisional Sign-Off)  
Division of General Restorative Devices  
510(k) Number K974807