OCT 21 1998

K982936

510(k) Premarket Notification
Summary of Safety and Effectiveness
for the
Osteonics® Extended Femoral Bearing Head

Submission Information:

Name and Address of the Sponsor of the 510(k) Submission:	Osteonics Corporation 59 Route 17 Allendale NJ 07401-1677
Contact Person:	Marybeth Naughton Regulatory Affairs Team Member
Date of Summary Preparation:	August 20, 1998

Device Identification

Proprietary Name:	Osteonics® Extended Femoral Bearing Head
Common Name:	Modular Femoral Bearing Head
Classification Name/Reference:	Hip Joint, Metal/Polymer, Semi-constrained, Cemented Prosthesis 21 CFR §888.3350

Predicate Device Identification:

The Osteonics® Extended Femoral Bearing Heads are substantially equivalent to the following predicate devices: The Osteonics® Morse Taper Heads, the Osteonics® C-Taper Heads, and the DePuy Articule-Eze® Total Hip Balls.

Description of Devices:

The Osteonics® Extended Femoral Bearing Heads are ASTM F-799 Cobalt chromium alloy devices available in two female taper configurations, a Morse Taper and a European Taper (Osteonics' trade name "C-Taper"). The devices are spherical in design and are available in 22, 26, 28, and 32mm diameters with +12.5mm and +15mm neck extensions. The outer surface of the Osteonics® Extended Femoral Bearing Heads are highly polished and are available both with and without nitrogen ion surface treatment.

Intended Use:

The Osteonics® Extended Femoral Bearing Heads are indicated for single-use in patients requiring either a Total Hip Replacement or a Hemi- or Bipolar Hip Replacement. The Osteonics® Extended Femoral Bearing Heads are intended to be used with a specific listing of Osteonics® femoral stems identified in Attachment 1 and are designed to accommodate a patient population requiring the extended offset in order to restore ligamentous balance.

Statement of Technological Comparison:

The design, materials, and intended use of the Osteonics® Extended Femoral Bearing Heads are substantially equivalent in design, materials and intended use to the predicate Osteonics® Morse Taper Heads, the Osteonics® C-Taper Heads and the DePuy Articule-Eze® Total Hip Balls.

Performance Data:

The comparison of the Osteonics® Extended Femoral Bearing Head to predicate systems which have been determined to be substantially equivalent through 510(k) premarket notifications demonstrates that no additional performance data are necessary.

ATTACHMENT 1 (Page 1)

Osteonics® Femoral Stems to be used with Osteonics® Extended Femoral Bearing Heads

Catalog Number	Description
S-1162-HFXX	CoCr Alloy, Plasma Sprayed, Omnifit, Collared, Normalized, Morse Taper Trunnion
1003-xxxx	CoCr Alloy, Satin Finish, Omnifit, Collarless, Normalized, Morse Taper Trunnion
1004-xxxx	CoCr Alloy, Satin Finish, Omnifit, Collared, Normalized, Morse Taper Trunnion
1005-xxxx	Ti6Al-4V Alloy, Satin Finish, Omnifit, Collarless, Normalized, Morse Taper Trunnion
1006-xxxx	Ti6Al-4V Alloy, Satin Finish, Omnifit, Collared, Normalized, Morse Taper Trunnion
1012-xxxx	Ti6Al-4V Alloy, Satin Finish, Omnifit, Collared, Normalized, Morse Taper Trunnion
1017-xxxx	Ti6Al-4V Alloy, HA Coated, Omnifit, Collarless, Normalized, Morse Taper Trunnion
1044-xxxx	CoCr Alloy, Satin Finish, Omnifit, Collared, Normalized, Morse Taper Trunnion
1045-xxxx	Ti6Al-4V Alloy, Satin Finish, Omnifit, Collarless, Normalized, Morse Taper Trunnion
1046-xxxx	Ti6Al-4V Alloy, Satin Finish, Omnifit, Collared, Normalized, Morse Taper Trunnion
1055-xxxx	Ti6Al-4V Alloy, HA Coated, Omnifit, Collared, Normalized, Morse Taper Trunnion
1092-xxxx	Ti6Al-4V Alloy, HA Coated, Omnifit, Collarless, Normalized, Morse Taper Trunnion
1093-xxxx	Ti6Al-4V Alloy, HA Coated, Omnifit, Collared, Normalized, Morse Taper Trunnion
1094-xxxx	Ti6Al-4V Alloy, HA Coated, Omnifit, Collarless, Normalized, Morse Taper Trunnion
21-xxxx	CoCr Alloy, Satin Finish, Omnifit, Collared, Smooth, Morse Taper Trunnion
6005-xxxx	Ti6Al-4V Alloy, Satin Finish, Omnifit, Collarless, Normalized, C-Taper Trunnion
6006-xxxx	Ti6Al-4V Alloy, Satin Finish, Omnifit, Collared, Normalized, C-Taper Trunnion
6010-xxxx	CoCr Alloy, Satin Finish, Omnifit, Collared, Normalized, C-Taper Trunnion
6017-xxxx	Ti6Al-4V Alloy, HA Coated, Omnifit, Collarless, Normalized, C-Taper Trunnion
6025-xxxx	Ti6Al-4V Alloy, Satin Finish, Omnifit, Collarless, Normalized, C-Taper Trunnion
6026-xxxx	Ti6Al-4V Alloy, Satin Finish, Omnifit, Collared, Normalized, C-Taper Trunnion
6033-xxxx	CoCr Alloy, Satin Finish, Omnifit, Collarless, Normalized, C-Taper Trunnion

ATTACHMENT 1 (PAGE 2)

Osteonics® Femoral Stems to be used with Osteonics® Extended Femoral Bearing Heads

Catalog Number	Description
6034-xxxx	CoCr Alloy, Satin Finish, Omnifit, Collared, Normalized, C-Taper Trunnion
6070-xxxx	CoCr Alloy, Grit Blasted, Omnifit, Collared, Smooth, C-Taper Trunnion
6072-xxxx	CoCr Alloy, Rough Finish, Omnifit, Collared, Smooth, C-Taper Trunnion
6079-xxxx	CoCr Alloy, Satin Finish, Omnifit, Collared, Smooth, C-Taper Trunnion
6088-xxxx	CoCr Alloy, Satin Finish, Omnifit, Collared, Normalized, C-Taper Trunnion
S0853-HF0x	CoCr Alloy, Grit Blasted, Omnifit, Collarless, Smooth C-Taper Trunnion
S1003-xxxx	CoCr Alloy, Plasma Sprayed, Omnifit, Collarless, Normalized, Morse Taper Trunnion
S1003-xxxx-A	CoCr Alloy, Satin Finish, Omnifit, Collarless, Normalized, Morse Taper Trunnion
S1003-xxxx-C	CoCr Alloy, Satin Finish, Omnifit, Collarless, Normalized, Morse Taper Trunnion
S1003-xxxx-D	CoCr Alloy, Satin Finish, Omnifit, Collarless, Normalized, Morse Taper Trunnion
S1012-xxxx-A	Ti6Al-4V Alloy, Satin Finish, Omnifit, Collarless, Normalized, Morse Taper Trunnion
S1149-xxxx	Ti6Al-4V Alloy, HA Coated, Omnifit, Collared, Normalized, Morse Taper Trunnion
S1296-HF0x	Ti6Al-4V Alloy, Satin Finish, Omnifit, Collared, Normalized, Morse Taper Trunnion
S1414-xxxx	CoCr Alloy, Grit Blasted, Omnifit, Collared, Smooth, C-Taper Trunnion
S1456-xxxx	Ti6Al-4V Alloy, Satin Finish, Omnifit, Collared, Normalized, Morse Taper Trunnion
S1462-HF0x	CoCr Alloy, Grit Blasted, Omnifit, Collared, Smooth, C-Taper Trunnion
S1966-xxxx	CoCr Alloy, Satin Finish, Omnifit, Collarless, Normalized, C-Taper Trunnion
S21-xxxx	CoCr Alloy, Satin Finish, Omnifit, Collared, Smooth, Morse Taper Trunnion
S21-xxxx-A	CoCr Alloy, Satin Finish, Omnifit, Collared, Smooth, Morse Taper Trunnion
S21-xxxx-B	CoCr Alloy, Satin Finish, Omnifit, Collared, Smooth, Morse Taper Trunnion
S21-xxxx-C	CoCr Alloy, Satin Finish, Omnifit, Collarless, Smooth, Morse Taper Trunnion
S2591-xxxx	CoCr Alloy, Satin Finish, Omnifit, Collared, Normalized, C-Taper Trunnion

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 1998

Ms. Elizabeth A. Staub
Director, Quality Assurance and Regulatory Affairs
Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K982936
Trade Name: Osteonics® Extended Femoral Bearing Head
Regulatory Class: II
Product Code: LWJ
Dated: August 20, 1998
Received: August 21, 1998

Dear Ms. Staub:

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,

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): K982936

Device Name: Osteonics® Extended Femoral Bearing Head

Indications For Use:
The Osteonics® Extended Femoral Bearing Heads are intended for single use in patients requiring either a Total Hip Replacement or Hemi- or Bipolar Hip Replacement. The Osteonics® Extended Femoral Bearing Heads are designed to accommodate a patient population requiring extended offset provided by a plus 12.5mm or a plus 15mm femoral head option when used in conjunction with the Osteonics® Femoral Stems specified in this submission.

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.

Other considerations for use as a Bipolar or Hemi-Hip Replacement:

- 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes
(per 21 CFR 801.109)

OROver-The-Counter Use No
(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982936