K983226

DEC 4 1998

510(k) Premarket Notification
Summary of Safety and Effectiveness
for the
Osteonics® X Cemented Hip Stem Series

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:	September 14, 1998

Device Identification

Proprietary Name:	Osteonics® X Cemented Hip Stem Series
Common Name:	Artificial Hip Component
Classification Name/Reference:	Hip Joint, Metal/Polymer, Semi-constrained, Cemented Prosthesis 21 CFR §888.3350

Predicate Device Identification:

The Osteonics® X Cemented Hip Stem Series are substantially equivalent to the following predicate devices: The Osteonics® Omnifit®-X Cemented Hip Stem and the Osteonics® Omnifit®-X Plus Cemented Hip Stems are substantially equivalent to the Osteonics® Omnifit® Plus Hip Stems and the Osteonics® Omnifit®-C Hip Stems and the Osteonics® ODC™-X Cemented Hip Stems and the Osteonics® ODC™-X Plus Cemented Hip Stems are substantially equivalent to the Osteonics® ODC™ Hip Stems and the Osteonics® ODC™ Plus Hip Stems.

Description of Devices:

The Osteonics® X Cemented Hip Stem Series are a series of cemented hip stems designed to meet requirements of a wide range of patients requiring cemented hip arthroplasty. All components are manufactured from ASTM F-799 Cobalt chromium alloy. The Osteonics® Omnifit®-X Cemented Hip Stems and the Osteonics® Omnifit®-X Plus Cemented Hip Stems

have a 132 degree neck angle and 127 degree neck angle respectively. They employ a satin finish, polished neck, forged proximal centralizer, and distal flutes and are available in sizes 4 through 11. The Osteonics® ODC™-X Cemented Hip Stems and the Osteonics® ODC™-X Plus Cemented Hip Stems have a 132 degree neck angle and 127 degree neck angle respectively. They employ a satin finish, forged proximal centralizer, and distal hole for use with optional cement spacer and are available in sizes 5 through 11.

Intended Use:

The Osteonics® X Cemented Hip Stem Series are intended for single use in patients requiring either a Total Hip Replacement or Hemi- or Bipolar Hip Replacement. The Osteonics® X Cemented Hip Stem Series are intended to provide a variety of options as a means for the Orthopaedic Surgeon to obtain an implant-to-patient match designed to provide reproducible cemented hip arthroplasty when used in conjunction with the Osteonics® Femoral Bearings with C-Taper geometry specified in this submission.

Statement of Technological Comparison:

The design, materials, and intended use of the Osteonics® X Cemented Hip Stem Series are substantially equivalent in design, materials and intended use to the predicate devices. The Osteonics® Omnifit®-X Cemented Hip Stem and the Osteonics® Omnifit®-X Plus Cemented Hip Stems are substantially equivalent to the Osteonics® Omnifit® Plus Hip Stems and the Osteonics® Omnifit®-C Hip Stems and the Osteonics® ODC™-X Cemented Hip Stems and the Osteonics® ODC™-X Plus Cemented Hip Stems are substantially equivalent to the Osteonics® ODC™ Hip Stems and the Osteonics® ODC™ Plus Hip Stems.

Performance Data:

Performance data for the Osteonics® X Cemented Hip Stem Series provided in this submission demonstrates the substantial equivalence to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 4 1998

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

Re: K983226
Osteonics® X Cemented Hip Stem Series
Regulatory Class: II
Product Code: JDI
Dated: September 14, 1998
Received: September 15, 1998

Dear Ms. Staub:

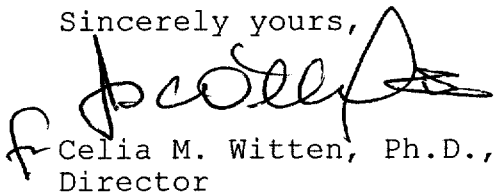
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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): K983226

Device Name: Osteonics® X Cemented Hip StemSeries

Indications For Use:
The Osteonics® X Cemented Hip Stems Series are intended for single use in patients requiring either a Total Hip Replacement or Hemi- or Bipolar Hip Replacement. The Osteonics® X Cemented Hip Stem Series are intended to provide a variety of options as a means for the Orthopaedic Surgeon to obtain an implant-to-patient match designed to provide reproducible cemented hip arthroplasty when used in conjunction with the Osteonics® Femoral Bearings with C-Taper geometry 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 X OROver-The-Counter Use _____ (per21CFR 801.109(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983226