DEC 11 1998

K983382

510(k) Premarket Notification
Summary of Safety and Effectiveness
for the
Osteonics® HA Generation II Acetabular Component System

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 23, 1998

Device Identification

Proprietary Name:	Osteonics® HA Generation II Acetabular Component System
Common Name:	Artificial Acetabular Component
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 Osteonics® HA Generation II Acetabular Component System is substantially equivalent to the Osteonics devices, which have previously been determined substantially equivalent by FDA:

- Osteonics® Secur-Fit™-HA Acetabular Components (previously known as the Osteonics® Secur-Fit™ AD-HA Acetabular Component System.
- Osteonics® Modular Acetabular Cup System.
- Osteonics® Secur-Fit™ HA X'tra Acetabular Component System.
- Osteonics® Threaded HA Acetabular Shells.
- Osteonics® Omnifit® Series II Cup Inserts.

Device Description

The Osteonics® HA Generation II Acetabular Component System consists of single-use devices. Each Osteonics® HA Generation II Acetabular Component consists of two pieces: an Osteonics® HA Generation II Acetabular Shell and an Osteonics® Generation II Cup Insert. The metal shell is intended for cementless fixation within the prepared acetabulum.

The Osteonics® HA Generation II Acetabular Shells are characterized by the following features:

- A basic dual radius (Secur-Fit option) or hemispherical (Threaded option) design
- The predicate interior geometry which allows a mating polyethylene insert size to be used with more than one shell size.
- A variety of screw hole patterns, including dome hole and peripheral screw holes.
- A dome hole which is compatible with the optional, currently marketed Osteonics® Acetabular Dome Hole Plugs.
- Circumferential normalizations (Secur-Fit option) or Circumferential threads (Threaded option)
- A wide range of sizes.
- Osteonics' AD-HA coating (Secur-Fit option) or HA coating (Threaded option)
- Compatibility with the Generation II Cup Insert

The Osteonics® Generation II Cup Inserts are characterized by the following features:

- A wireless locking mechanism which utilizes a continuous ridge which locks into a groove on the interior of the mating shell.
- A hemispherical geometry which is designed to maximize liner conformity to mating shell.
- Increased indexability through mating of barbs on shell with scalloped areas on insert.

Intended Use:

The Osteonics® HA Generation II Acetabular Components are single-use devices. The shells are intended for cementless fixation within the prepared acetabulum. The Osteonics® HA Generation II Acetabular Component System is compatible with any appropriately selected Osteonics hip stem/femoral head combination.

Indications:

The indications for the use of the Osteonics® HA Generation II Acetabular Components, in keeping with those of other legally marketed Osteonics acetabular components, are as follows:

- 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.

- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Statement of Technological Comparison:

The substantial equivalence of the Osteonics® HA Generation II Acetabular Components to the predicate devices identified above—in terms of intended use, materials, and design features—is based on the following.

Intended Uses:

The Osteonics® HA Generation II Acetabular Components, like the predicate acetabular components cited above, are intended for cementless fixation. The subject devices and the predicate devices share the same indications for use.

Materials:

The Osteonics® HA Generation II Acetabular Shells are fabricated from ASTM F-620 Titanium Ti6Al-4VEli Alloy which is different from the predicate acetabular shells cited above which are fabricated from ASTM F-67 CP Titanium, but identical to other Osteonics' products, such as the Osteonics Titanium Femoral Stems, which have a long history of biocompatibility and clinical performance. The Osteonics® Secur-Fit™ -HA Generation II Acetabular Shells feature Osteonics' AD-HA coating (arc-deposited CP Ti, beneath plasma-sprayed hydroxylapatite) as do predicate Osteonics® Secur-Fit™-HA Acetabular Shells, Osteonics® Modular Acetabular Component System, and Osteonics® Secur-Fit™-HA X'tra Acetabular Component System. The Osteonics® Threaded-HA Acetabular Generation II Acetabular Shell features the Osteonics' HA coating (plasma sprayed HA) as does the predicate Osteonics® Threaded-HA Acetabular Shells.

The Osteonics® Generation II Cup Inserts and the predicate Osteonics® Omnifit® Series II Cup Inserts are both manufactured from ultra-high molecular weight polyethylene.

Design:

The Osteonics® HA Generation II Acetabular Shells maintain design features consistent with the predicate Osteonics® Acetabular Components as follows:

A basic dual radius (Secur-Fit™ option) or hemispherical (Threaded option) design.

- A variety of screw hole patterns, including dome screw holes and peripheral screw holes.
- A dome hole which is compatible with the optional, currently marketed Osteonics® Acetabular Dome Hole Plug.
- Circumferential normalizations (Secur-Fit™ option) or circumferential threads (Threaded option).
- A wide range of sizes.
- Osteonics AD-HA coating (Secur-Fit™ option) or HA coating (Threaded option).
- A locking mechanism which maintains or exceeds the strength characteristics of predicate devices.

The Osteonics® Generation II Cup Inserts are characterized by the following design features which are consistent with predicate inserts:

- Availability in 22mm, 26mm, 28mm, and 32mm inner diameter with the same minimum polyethylene thickness.
- Availability in 0 degree and 10 degree insert versions.
- Availability with 2mm offset and 6mm (eccentric offset configurations.
- A comparable rotating locking mechanism to predicate devices which utilizes the mating of barbs on the shell to scalloped areas on the insert.
- Indexability of insert within the shell to provide ease of alignment of mating insert/shell.

Summary

Based on the similarities presented above, the supporting testing reproduced in Appendix C, and the fact that the Osteonics® HA Generation II Acetabular Components employ standard sterilization and packaging methods, the substantial equivalence of the Osteonics® HA Generation II Acetabular Components to other legally marketed, class II, acetabular components is demonstrated.

Performance Data:

The performance characteristics of the "AD-HA" and "HA" coatings have been presented in predicate 510(k) submissions. Mechanical testing of the subject shell/insert locking mechanism and fatigue performance is provided in this submission and demonstrate substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 1998

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

Re: K983382
Osteonics® HA Generation II
Acetabular Component System
Regulatory Class: II
Product Code: MEH
Dated: September 24, 1998
Received: September 25, 1998

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). This decision is based on consideration of the specific design of cup and coating composition detailed in this application. You may, therefore, market the device, subject to the general controls provisions of the Act and the following limitation:

> You may not label or in any way promote these devices for "biological attachment, enhanced clinical or radiographic performance, enhanced fixation and/or long-term stable fixation." The data presented support equivalence with no additional claims over a conventional press-fit hip prosthesis (i.e., mechanical interlock, only).

Additional limitations for more specific claims of safety and effectiveness may be forthcoming. Should additional limitations be applied you will be contacted in writing to inform you of the additional labeling limitations.

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.

You may market your device under the above limitations as class II devices. These devices would be considered not substantially equivalent to a legally marketed predicate device if labeled with other intended uses and/or claims of safety or effectiveness. Any other intended uses or claims may cause the device to be classified into Class III under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing.

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. 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 immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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,

for 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): K983382

Device Name: Osteonics® HA Generation II Acetabular Component System

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- 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.

(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 K983382

Prescription Use X

OROver-The-Counter Use _____ (per21CFR 801.109(Optional Format 1-2-96)