

MAY 22 1997

K971422

Osteonics® Acetabular Wedge System

510(k) Summary

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Osteonics® Acetabular Wedge System

Submission Information

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

Contact Person: Terry Sheridan
Regulatory Affairs Specialist

Date of Summary Preparation: April 15, 1997

Device Identification

Proprietary Name: Osteonics® Acetabular Wedge System

Common Name: Acetabular augmentation devices for total hip replacement acetabular 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 Osteonics® Acetabular Wedges are substantially equivalent to the following competitive and/or Osteonics devices, which have previously been determined substantially equivalent by FDA:

- The MARS (Modular Acetabular Reconstruction System) Device
- The Osteonics® Secur-Fit™ HA Acetabular Shells

Device Description

The Osteonics® Acetabular Wedges are characterized by the following design features.

- **Basic Wedge Shape:** The Osteonics® Acetabular Wedges feature a basic wedge (or crescent) shape that conforms to the outer geometry of the mating acetabular shell.
- **Size range:** The Osteonics Acetabular Wedges are available in a wide range of outer diameter sizes.
- **Thickness Options:** The Osteonics® Acetabular Wedges come in thicknesses of 8, 12, or 16mm.
- **Interior Normalizations:** The interior face of the acetabular wedges features machined steps that correspond to the normalizations featured on the exterior of the mating shells.
- **Screw Hole Availability:** The Osteonics® Acetabular Wedges feature 6.5mm bone screw holes that are compatible with commercially available Osteonics 6.5mm Cancellous Bone Screws.
- **Surface Treatments:** The exterior surface of the Osteonics® Acetabular Wedges features Osteonics' AD-HA Coating.

Intended Use:

General

The Osteonics® Acetabular Wedges will provide the orthopedic surgeon with a prosthetic alternative to structural allografting in cases of segmental acetabular deficiencies.

Indications

The Osteonics® Acetabular Wedges, because they are accessory components to an existing total hip replacement system, are subject to the general indications and contraindications of their mating acetabular shell components, as follows:

General Indications for Total Hip Replacement 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 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.

Indications Specific to the Acetabular Wedges

- As an alternative to structural allograft in cases of superior and superior/posterior segmental acetabular deficiencies.

Assembly

The Osteonics® Acetabular Wedges are intended for intraoperative assembly to mating acetabular shells. The operating room staff will use polymethyl methacrylate (PMMA) bone cement to affix a selected acetabular wedge to its mating acetabular shell.

Fixation

The assembled acetabular wedge-to-shell construct can be affixed to the acetabulum either with or without bone cement, according to the specific fixation methods already determined substantially equivalent by FDA for the commercially available, mating acetabular shell components.

Statement of Technological Comparison:

The substantial equivalence of the Osteonics Acetabular Wedges is supported by a comparison of the subject device to the above-cited predicate devices.

A comparison of the subject and predicate devices in terms of intended use, materials, and design follows.

Intended Use

Both the subject devices and the predicate MARS devices are intended to provide an alternative to structural allograft in cases of segmental acetabular deficiencies. Use of the subject wedges in an acetabular construct that can be affixed to the acetabulum either with or without bone cement is predicated by the mating acetabular shells, which have already been determined Substantially Equivalent by FDA for either cemented or cementless fixation.

Materials*Substrate materials*

The subject device and the predicate devices feature substrates manufactured from commercially pure titanium.

Coating materials

The Osteonics® Acetabular Wedges feature Osteonics' AD-HA coating. This coating has already been extensively characterized by Osteonics and has already been thoroughly reviewed by FDA on several previous occasions.

Design

The subject devices, like the predicate MARS devices, are modular wedges which come in a variety of widths and thicknesses. Both device systems are intended for intraoperative assembly to an otherwise hemi-spherical shell design. The subject devices are assembled to their mating shells via PMMA bone cement, while the predicate MARS devices are assembled

to their mating shells via a taper and screw mechanism. This difference, however, is not significant because the assembly method of the subject devices has been shown to withstand anticipated physiologic loading conditions.

Performance Data:

The Osteonics® Acetabular Wedges have been tested to ensure that the wedge-to-shell assembly is strong enough to withstand anticipated in-vivo loading conditions. All specimens successfully endured 10 million cycles of physiologically relevant loading, with no signs of impending wedge/shell interface failure.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 1997

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

Re: K971422
Acetabular Wedge System
Regulatory Class: II
Product Codes: MEH and LPH
Dated: April 15, 1997
Received: April 17, 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). This decision is based on consideration of the specific design of stem 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

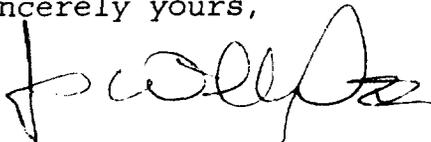
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the 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

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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,



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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 9 7 1 4 2 2

Device Name: Osteonics® Acetabular Wedge System

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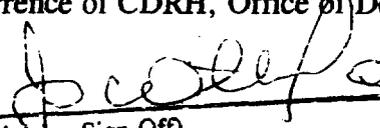
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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K971422

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)