

APR 29 1998

K980774

**510(k) Premarket Notification  
Summary of Safety and Effectiveness  
for the  
Osteonics® GAP-II Restoration Acetabular Shells**

**Submission Information**

**Name and Address of the Sponsor  
of the 510(k) Submission:**

Osteonics Corporation  
59 Route 17  
Allendale, NJ 07401-1677

**Contact Person:**

Kate Sutton  
Regulatory Affairs Specialist

**Date of Summary Preparation:**

February 26, 1998

**Device Identification**

**Proprietary Name:**

Osteonics® GAP-II Restoration  
Acetabular Shells

**Common Name:**

Acetabular Shell

**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® GAP-II Restoration Acetabular Shells employ features which are substantially equivalent to features of the following Osteonics predicate device, which has been cleared for marketing via the 510(k) process:

- Osteonics® Restoration Acetabular Cup Series

## **Device Description**

The Osteonics® GAP-II and GAP-IIS Restoration Acetabular Shells are single use components which are intended for placement within the acetabulum, and which are intended to provide an articulating surface for corresponding Osteonics' femoral head/stem components. The two iliac plates on the GAP-IIS shell are shorter than those of the GAP-II shell. Each Osteonics® GAP-II or GAP-IIS Restoration Acetabular Cup is assembled from two separate components: an Osteonics® GAP-II or GAP-IIS Restoration Acetabular Shell and a predicate Osteonics® Omnifit® Cup Insert, ABC Cementable Polyethylene Insert, Osteonics® Concentric Polyethylene Acetabular Cup, or Osteonics® Flanged Polyethylene Acetabular Cup. The polyethylene cups and inserts are intended to be affixed to the shell via polymethylmethacrylate (PMMA) bone cement.

The Osteonics® GAP-II and GAP-IIS Restoration Acetabular Shells are manufactured from ASTM F-67 Commercially Pure Titanium (CP Ti). The shells are available in a range of outer diameter shell sizes. The Osteonics® GAP-II and GAP-IIS Restoration Acetabular Shells feature a basic spherical geometry, 18 to 26 acetabular dome screw holes (depending on the size of the shell), two superior plates, a 20° superior/posterior hood, an inferiorly located acetabular notch hook, a satin-finished interior surface, and a grit-blasted exterior surface.

Bone screws placed through the dome and/or lip of the acetabular shell are used to secure the Osteonics® GAP-II or GAP-IIS Restoration Acetabular Shell within the prepared acetabulum. The shells are designed to allow some of the bone cement (used to fix the polyethylene liner to the shell) to be extruded through any unoccupied acetabular dome screw holes. In addition to traditional acetabular dome screws, and in order to further enhance the potential for initial and long term stable shell fixation despite large bony defects, the Osteonics® GAP-II and GAP-IIS Restoration Acetabular Shells employ an inferior hook, superior plates, and a superior/posterior hood. The inferior hook is crimped around the acetabular notch. The shell hood covers the superior rim of the acetabular cavity, and the superior plates and can be secured to the acetabulum and/or ilium with Osteonics® 6.5mm Restoration GAP Plate Screws.

## **Intended Use:**

The Osteonics® GAP-II and GAP-IIS Restoration Acetabular Shells are total hip replacement components are intended to resurface the acetabulum, and are intended to be used in conjunction with commercially available Osteonics femoral stems and compatible Osteonics modular femoral bearing heads. The Osteonics® GAP-II and GAP-IIS Restoration Acetabular Shells are single-use devices. The metal shells are intended for screw fixation within the prepared acetabulum, while the polyethylene inserts are intended for cemented fixation within the metal shells. The Osteonics® GAP-II and GAP-IIS Restoration Acetabular Shells have been specifically designed to address cases involving major bony defects of the acetabulum which may require extensive reconstruction and bone grafting. The indications for the Osteonics® GAP-II and GAP-IIS Restoration Acetabular Shells include the following:

- 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.
- Bone stock which is of poor quality or which is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.
- Class III cavitary or segmental defects.

### **Performance Data:**

Mechanical testing has been performed to demonstrate the substantial equivalence of this Osteonics acetabular shell design to predicate acetabular shell designs in terms of its fatigue strength and shell/insert assembly method.

### **Statement of Technological Comparison:**

The features of the Osteonics® GAP-II or GAP-IIS Restoration Acetabular Shell, either alone or in combination, are substantially equivalent to corresponding features of Osteonics predicate device as follows.

The Osteonics® GAP-II and GAP-IIS Restoration Acetabular Shells are substantially equivalent, in terms of substrate material, indications for use, and availability of screw holes for the employment of acetabular screw fixation, to the legally marketed plated shell in the predicate Osteonics® Restoration Acetabular Cup Series.

The cup geometry of the Osteonics® GAP-II and GAP-IIS Restoration Acetabular Shells is spherical, and as such, is substantially equivalent in terms of its basic geometry to the predicate Osteonics® Restoration Acetabular Cup Series.

The inferior hook and superior plates of the Osteonics® GAP-II and GAP-IIS Restoration Acetabular Shells are substantially equivalent in terms of design and function to similar characteristics featured on the iliac plated cup version in the Osteonics® Restoration Acetabular Cup Series.

The inserts used with the Osteonics® GAP-II or GAP-IIS Restoration Acetabular Shells are the predicate Osteonics® Omnifit® Cup Inserts, Osteonics® Concentric Polyethylene Acetabular Cup, or Osteonics® Flanged Polyethylene Acetabular Cup. These inserts are assembled to the Osteonics® GAP-II or GAP-IIS Restoration Acetabular Cup Shells through the use of bone cement. This assembly method is predicated by the Osteonics® Restoration Acetabular Cups.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 29 1998

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

Re: K980774  
Trade Name: GAP-II Restoration Acetabular Shells  
Regulatory Class: LZO and JDI  
Product Code: II  
Dated: February 26, 1998  
Received: March 2, 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.

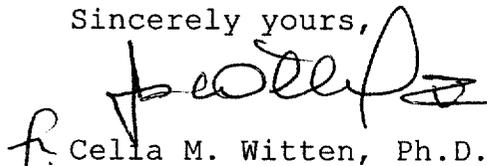
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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): K980774

Device Name: Osteonics® GAP-II Restoration Acetabular Shells

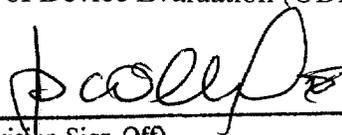
Indications For Use:

The indications for the use of the Osteonics® GAP-II Restoration Acetabular Shells, 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.
- Class III cavitary and segmental defects.

(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)



(Division Sign-Off)  
Division of General Restorative Devices

510(k) Number K980774

Prescription Use Yes  
(Per 21 CFR 801.109)

OR Over-The-Counter Use No

(Optional Format 1-2-96)