K970957

# 510(k) Premarket Notification
# Summary of Safety and Effectiveness
# for the
# Osteonics® Restoration Acetabular Ring

JUN - 3 1997

## 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:**

May 13, 1997

## Device Identification

**Proprietary Name:**

Osteonics® Restoration Acetabular Ring

**Common Name:**

Acetabular Shell

**Classification Name and Reference:**

Prosthesis, Hip, Acetabular Mesh
21 CFR §878.3300

## Predicate Device Identification

The Osteonics® Restoration Acetabular Ring employs 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® Restoration Acetabular Rings 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. Each Osteonics® Restoration Acetabular Ring is assembled from two separate components: an Osteonics® Restoration Acetabular Shell and a predicate Osteonics® Omnifit ® Cup Insert, Osteonics ®Concentric Polyethylene Acetabular Cup, or Osteonics® Flanged Polyethylene Acetabular Cup.

The bodies of the Osteonics® Omnifit® Cup Insert, Osteonics® Concentric Polyethylene Acetabular Cup, and Osteonics® Flanged Polyethylene Acetabular Cup are manufactured from Ultra High Molecular Weight Polyethylene (UHMWPE). The Osteonics® Omnifit® Cup Insert, Osteonics® Concentric Polyethylene Acetabular Cup, or Osteonics® Flanged Polyethylene Acetabular Cup, when used with the Osteonics® Restoration Acetabular Ring, is intended to be affixed to the shell via polymethylmethacrylate (PMMA) bone cement.

The Osteonics® Restoration Acetabular Rings 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® Restoration Acetabular Ring features a basic spherical geometry, thirteen or sixteen acetabular dome screw holes (depending on the size of the shell), a built up 20° superior lip, an inferiorly located acetabular notch hook, and satin-finished interior and exterior surfaces.

Bone screws placed through the dome and/or lip of the acetabular shell are used to secure the Osteonics® Restoration Acetabular Ring 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 small bony defects, the Osteonics® Restoration Acetabular Ring employs an inferior hook and a superior lip. The inferior hook is crimped around the acetabular notch. The superior lip of the shell covers the superior rim of the acetabular cavity and can be secured to the acetabulum with 6.5mm cancellous bone screws.

## Intended Use:

The Osteonics® Restoration Acetabular Rings are total hip replacement components which are intended to resurface the acetabulum, and which are intended to be used in conjunction with commercially available Osteonics femoral stems and compatible Osteonics modular femoral bearing heads. The Osteonics® Restoration Acetabular Rings 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® Restoration Acetabular Rings have been specifically designed to address cases involving minor bony defects of the acetabulum which may require moderate reconstruction and bone grafting. The indications for the Osteonics® Restoration Acetabular Rings 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 II cavitary or protrusio defects.

**Performance Data:**

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

**Statement of Technological Comparison:**

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

The Osteonics® 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, non-plated cup version in the predicate Osteonics® Restoration Acetabular Cup Series.

The cup geometry of the Osteonics® Restoration Acetabular Rings 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 lip of the Osteonics® Restoration Acetabular Rings are substantially equivalent in terms of design and function to similar characteristics featured on the non-plated cup version in the Osteonics® Restoration Acetabular Cup Series.

The bone screws which are required for use with Osteonics® Restoration Acetabular Ring are the 6.5mm Osteonics® Restoration GAP Plate Screws.

The inserts used with the Osteonics® Restoration Acetabular Ring 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® Restoration Acetabular Ring Shells through the use of bone cement. This assembly method is predicated by the Osteonics® Restoration Acetabular Cups.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 3 1997

Ms. Kate Sutton
Regulatory Affairs Specialist
Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K970957
Osteonics® Restoration Acetabular Ring
Regulatory Class: II
Product Codes: JDJ and JDI
Dated: March 14, 1997
Received: March 17, 1997

Dear Ms. Sutton:

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 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. 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,

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): K970957

Device Name: Osteonics® Restoration Acetabular Ring

Indications For Use:

The indications for the use of the Osteonics® Restoration Acetabular Rings, 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 II cavitary or protrusio defects.

(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 K970957

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)