K102019

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510(k) Summary

Sponsor	Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430
Contact Person	Karen Ariemma Project Manager, Regulatory Affairs/Regulatory Compliance Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5718
Date Prepared:	February 14, 2011
Proprietary Name:	Restoration Acetabular Wedge Augments
Common Name:	Acetabular Bone Augments
Classification Name:	21 CFR §888.3358 Prosthesis, hip, semi-constrained, metal/polymer, porous uncemented

Legally Marketed Device to Which Substantial Equivalence is Claimed:
Zimmer Trabecular Metal Augments K061067 and the Osteonics Acetabular Wedge System K971422.

Device Description:
Restoration Acetabular Wedge Augments provide options to address a wide range of bone deficiencies encountered in acetabular revision. The augments provide support for the shell in the acetabulum with superior and/or posterior defects. The augments are offered in various geometries and sizes to address wide defect ranges. The augments are made of commercially pure titanium porous sintered foam. The Restoration Acetabular Wedge Augments can be used with Restoration ADM, Secur-Fit, Trident, and Tritanium uncemented shells. The Restoration Acetabular Wedge Augments can be used with Trident all-polyethylene cemented cups

Intended Use:

The Restoration Acetabular Wedge Augments are intended for use as an alternative to structural allograft in cases of superior and superior/posterior segmental acetabular deficiencies.

Indications:

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.

Acetabular Augments are intended for cementless use only to the bone interface; and 2) are affixed to the mating cup using bone cement

Summary of Technologies: Device comparison showed that the proposed device is substantially equivalent in intended, use, materials and performance characteristics to the predicate device.

Non-Clinical Testing: Non-clinical laboratory testing was performed for the CP Titanium porous sintered foam to determine substantial equivalence. Non-clinical testing was provided as outlined in the FDA Guidance Document entitled "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement (28 April 1994)". The following mechanical testing was performed: tensile, compression, abrasion, and construct fatigue testing of the augment/shell construct. The following parameters of the CP Titanium porous sintered foam were determined: volume porosity, average pore size, mean intercept length and grain size. In addition, static compression strength, abrasion and morphological properties were determined post fatigue testing. There was no affect on mechanical morphological properties based on fatigue loading. The testing demonstrated that the Restoration Acetabular Wedge Augments are substantially equivalent to devices currently cleared for market.

Clinical Testing: Clinical testing was not required for this submission.

Conclusion: The Restoration Acetabular Wedge Augments are substantially equivalent to the predicate devices identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR - 3 2011

Howmedica Osteonics Corp.
% Ms. Karen Ariemma
Project Manager, Regulatory Affairs and Regulatory Compliance
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K102019
Trade/Device Name: Restoration Acetabular Wedge Augments
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH
Dated: February 14, 2011
Received: February 16, 2011

Dear Ms. Ariemma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102019

Device Name: Restoration Acetabular Wedge Augments

Indications for Use:

The indications for use of the Restoration Acetabular Wedge Augments:

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.
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Indications Specific to the Acetabular Wedges:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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