K103104

510(k) Summary of Safety and Effectiveness:
SPECIAL ORTHOPAEDIC SOLUTIONS GLENOID SHOULDER COMPONENT

NOV 2 2 2010

Proprietary Name: Shoulder Component	Special Orthopaedic Solutions Glenoid
Common Name:	Total Joint Shoulder Component
Classification Name and Reference:	Shoulder Joint Metal/Polymer Semi-Constrained Cemented Prosthesis 21 CFR §888.3660
Proposed Regulatory Class:	Class II
Product Codes:	87 KWS
For Information contact:	Avital Merl-Margulies Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-6365 Fax: (201) 831-3365
Date Prepared:	11/22/2010

Description:

The Special Orthopaedic Solutions Glenoid Shoulder Component is designed for use as the glenoid component in a total shoulder arthroplasty. The glenoid is manufactured from ASTM F-648 ultra high molecular weight polyethylene (UHMWPE) and features an x-ray marking wire on its medial surface manufactured from ASTM F-90 cobalt chromium alloy. The glenoid component will be offered in three sizes 5, 7, & 9 with a 10 degree posterior buildup. Additional size 9 glenoid components both with and without posterior buildup will also be offered with new peg geometry.

Intended Use:

The Special Orthopaedic Solutions Glenoid Shoulder Component is a single use device intended for cemented fixation within the prepared glenoid fossa of the shoulder.

Indications for Use:

The indications for use of the total shoulder arthroplasty include:

- Aseptic necrosis of the humeral head.
- Painful, disabling joint disease of the shoulder resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
- Proximal humeral fracture and/or dislocation.
- Revision of previous unsuccessful total shoulder replacement, resurfacing or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

The glenoid components are intended for cemented use only.

Proposed Modification:

The subject Special Orthopaedic Solutions Glenoid Shoulder Component has the same indications for and intended use, material, operational principles, and bearing sizes as the previously cleared Osteonics All Polyethylene Glenoid Shoulder Component cleared under K950521. The subject Special Orthopaedic Solutions Glenoid Shoulder Component device consists of a rotation to the bearing surface of the implant to increase the posterior thickness to help restore joint alignment. Additional size 9 glenoid components both with and without posterior buildup will also be offered with a modified peg geometry.

Summary of Data:

Testing has been performed to demonstrate equivalence of the subject device to its predicate device. The testing includes dynamic evaluation of glenoid loosening via ASTM F2028-08 and an engineering analysis on the polyethylene thickness.

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

Howmedica Osteonics Corporation
% Ms. Avital Merl-Margulies
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

NOV 2 2 2010

Re: K103104
Trade/Device Name: Special Orthopaedic Solutions Glenoid Shoulder Component
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS
Dated: October 14, 2010
Received: October 20, 2010

Dear Ms. Merl-Margulies:

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.

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

NOV 2 2 2010

510(k) Number (if known): K103104

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (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)

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

510(k) Number K103104