K103835

MAY -5 2011

510(k) Summary

Sponser:	Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430
Contact Person:	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:	May 3, 2011
Proprietary Name:	ReUnion® Total Shoulder Arthroplasty (TSA) System
Common Name:	Artificial Shoulder Components
Classification Name	21 CFR §888.3660: Shoulder Joint Metal/Polymer Semi Constrained Cemented Prosthesis 21 CFR §888.3690: Shoulder Joint Humeral (hemi-shoulder) metallic uncemented prosthesis
Proposed Regulatory Class:	Class II
Product Codes:	87KWS: Prosthesis, shoulder, semi-constrained, metal/polymer, uncemented 87HSD: Prosthesis, shoulder, hemi-humeral, metallic, cemented

Legally marketed device to which substantial equivalence is claimed:
Osteonics Shoulder Humeral Components: K955731
Solar ReUnion Fracture Stem: K062113
Osteonics All Polyethylene Glenoid Shoulder Component: K950521
Osteonics All Polyethylene Glenoid Shoulder Component: K962082
Solar Shoulder Offset Humeral Head: K001419
Osteonics Solar Shoulder Humeral Bearing Head: K990598
Depuy Global Advantage Shoulder, Global Advantage Humeral Stem, Global Advantage Eccentric Head: K992065
Depuy Global Shoulder Crosslinked Glenoid: K052472
DVO Extremity Solutions Total and Hemi Shoulder System: K060988

Device Description:
The subject Reunion® Total Shoulder Arthroplasty (TSA) System is intended for shoulder arthroplasty. The components of this system consist of humeral stems, a

modular neck adapter, single radius heads, and self pressurizing glenoids (SPG). The humeral stem components will be manufactured from titanium alloy according to ASTM F136 and will be offered in both cemented and cementless designs. The cementless humeral stem design will feature a circumferential plasma spray and hydroxyapatite (HA) coating and be offered in 7mm-17mm distal diameters in 1mm increments. The cemented humeral stems will be offered in 6mm-15mm distal diameters in 1mm increments and will also include 4 longer stems with distal diameters 6mm-12mm in 2 mm increments. These humeral stems were designed to mate with the subject single radius heads or the modular neck adapter, manufactured from cobalt chrome according to ASTM F1537, for compatibility with other marketed humeral heads. The single radius heads will be manufactured from cobalt chrome according to ASTM F75 and will be offered in spherical diameter head sizes 40mm-56mm in 4mm increments for both standard and eccentric designs. The self pressuring glenoids (SPG) will be manufactured from X3® polyethylene according to ASTM F648 and will mate with the single radius heads. The SPGs will be offered in both pegged and keeled configurations ranging from 40mm-56mm spherical diameters in 4mm increments.

Intended Use:
The Reunion® TSA System components are sterile, single-use devices intended for use in primary and revision total shoulder arthroplasty to alleviate pain and restore function. The subject humeral stems will be offered in both cemented and cementless applications. The self pressurizing glenoid components are intended for cemented use only.

Indications for Use:

For use as a Hemi or Total Shoulder Replacement:

- 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 fractures and/or dislocation.
- Clinical management problems where arthodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Revision of previous unsuccessful total shoulder replacement, resurfacing or other procedure.

The gleonid components are intended for cemented use only.

Summary of Technologies:
The technological characteristics (material, design, sizes, and operational principles) of the ReUnion® TSA System components are similar or identical to its predicate devices.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The following mechanical tests were conducted according to ASTM F2028-08: Fatigue strength on humeral components and dynamic evaluation of glenoid loosening on the glenoids. The testing demonstrated that the ReUnion® TSA

system components met performance requirements and are as safe and effective as their predicate devices.

Clinical Testing:
None provided as a basis for substantial equivalence

Conclusion
The ReUnion® TSA System is 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

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

MAY - 5 2011

Re: K103835
Trade/Device Name: ReUnion® Total Shoulder Arthroplasty (TSA) System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, HSD
Dated: April 29, 2011
Received: May 2, 2011

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. 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.

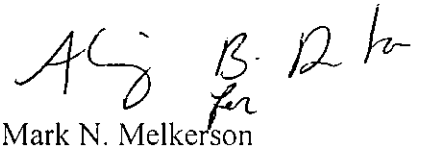
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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): K103835

Device Name: ReUnion® Total Shoulder Arthroplasty (TSA) System

For use as a Hemi or Total Shoulder Replacement:

- 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 fractures and/or dislocation.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Revision of previous unsuccessful total shoulder replacement, resurfacing or other procedure.

The gleonid components are intended for cemented use only. The humeral stem components are intended for both cemented and cementless use.

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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