

510(k) Summary

MAR - 1 2011

Manufacturer: Global Manufacturing Technology
8-10 Resolution Drive
Unanderra NSW 2526
AUSTRALIA
Phone: (011) 61 (2) 4272 4493

Device Trade Name: MSA Hip System

Contact: Mr. Ricardo Lucchini
Director Of Regulatory Affairs

Prepared By: Musculoskeletal Clinical Regulatory Advisers, LLC
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Date Prepared: February 10, 2011

Classification: 21 CFR 888.3353

Hip joint metal/ceramic/polymer semi-constrained
cemented or nonporous uncemented prosthesis

Class II

Product Codes: MEH

Indications For Use: The MSA Hip System is indicated for cementless use and is intended to replace a hip joint.

The device is intended for:

- skeletally mature individuals undergoing primary surgery for total hip replacement
- patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fracture of the femur.
- patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis
- patients suffering from disability due to previous fusion
- patients with acute femoral neck fractures

Device Description: The MSA Hip System is a modular hip system consisting of a short stem which mates with a modular neck. The proximal portion of the stem has a plasma spray coating and a hydroxyapatite coating. The MSA Hip System can be mated with a number of previously cleared femoral heads and acetabular components. The hip system is intended for cementless implantation.

Materials: The hip stems are made of Ti-6Al-4V (ASTM F136) with a commercially pure titanium plasma spray coating (ASTM F1580) and the modular necks are made of CoCr alloy (ASTM F1537).

Predicate Devices: Comparative information presented in the 510(k) supports the substantial equivalence of the MSA Hip System with respect to its indications for use, design, materials, and method of fixation. This 510(k) demonstrates the substantial equivalence of the MSA Hip System to the following predicate devices: Aesculap Implant System's Metha Short Stem Hip System (K071916 and K080584); Zimmer's Mayo Conservative Hip Prosthesis (K030733 and K943230); Wright Medical Technology's PROFEMUR Hip System (K081090 and K091423); and OMNI life science, Inc.'s Apex ARC™ Hip System (K090845).

The MSA Hip Stem shares the same indications for use for which the predicate systems were cleared. The geometry and design of the subject hip stem matches that of the predicate hips. The materials of the stem and neck are the same and the predicate stems and necks. Like the MSA Hip, the majority of the predicate stems are intended for cementless fixation.

Performance Data: The non-clinical tests performed by the company include neck endurance, stem fatigue, interconnection strength of modular connections, and ROM testing. The test results demonstrate that the MSA Hip System is substantially equivalent to legally marketed predicate devices.



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

Global Manufacturing Technology
% Musculoskeletal Clinical Regulatory Advisers, LLC
Hollace S. Rhodes
Director, Orthopedic Regulatory Affairs
1331 H St NW, 12th Floor
Washington DC, 20005

MAR - 1 2011

Re: K102172

Trade/Device Name: MSA Hip System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: MEH
Dated: February 24, 2011
Received: February 25, 2011

Dear Ms. Rhodes:

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.

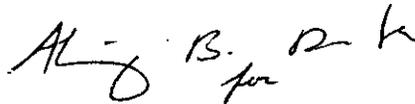
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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" (21 CFR 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,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson" with a stylized flourish at the end.

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

Enclosure

