K092406 (pg 1/3)

510(k) Summary of Safety and Effectiveness

Proprietary Name:	ABG™ II Modular Hip Stem NOV - 4 2009
Common Name:	Hip prosthesis
Classification Name and Reference:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, 21 CFR §888.3353 Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis, 21 CFR §888.3358 Hip joint metal/polymer semi-constrained cemented prosthesis 21 CFR §888.3350 Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis. 21 CFR §888.3390 Hip joint metal/polymer constrained cemented or uncemented prosthesis. 21 CFR §888.3310 Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis. 21 CFR §888.3360
Regulatory Class:	Class II
Product Codes:	87 MEH - prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate 87 LZO - prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented 87 LPH - prosthesis, hip, semi-constrained, metal/polymer, porous uncemented 87 JDI - prosthesis, hip, semi-constrained, metal/polymer, cemented 87 KWY - prosthesis, hip, hemi-, femoral, metal/polymer, cemented or uncemented 87 KWZ - prosthesis, hip, constrained, cemented or uncemented, metal/polymer 87 KWL - prosthesis, hip, hemi-, femoral, metal

(K092406 pg 2/3)

87 LWJ - prosthesis, hip, semi-constrained, metal/polymer, uncemented

For Information contact: Estela Celi, Regulatory Affairs Associate
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Phone: (201) 831-6461 Fax: (201) 831-3461

Date Prepared: August 8, 2009

Description:
Howmedica Osteonics is introducing a modular hip prosthesis. The basic design of the ABG™ II Modular Hip Stem, referred as the ABG™ II Modular, is similar to other total hip systems commercially distributed such as the Stryker Modular Hip System.

The subject hip stem is composed of a modular stem with a modular neck intended for cementless, press-fit application. It is designed for use with the currently available compatible Howmedica Osteonics' femoral heads, bipolars and their compatible acetabular components.

Intended Use:
The ABG™ II Modular Hip Stem is a sterile, single-use device intended for use in primary and revision total hip arthroplasty to alleviate pain and restore function. This device is intended to be used with any currently available compatible Howmedica Osteonics' acetabular components. Compatibility with the modular stems includes: V40 Biolox Delta, Biolox Delta Universal Taper Heads and Sleeves, V40 CoCr Heads, V40 LFIT CoCr Heads, C-Taper Alumina Heads when used with the V40/C-taper Adaptor, C-Taper Delta Heads when used with C-taper Adaptor, UHR Universal Head, Unitrax Heads when used with the Unitrax V40 Modular Adapter.

Indications:
The indications for use of total hip replacement prostheses include:

1) Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2) Rheumatoid arthritis;
3) Correction of functional deformity;
4) Revision procedures where other treatments or devices have failed; and,
5) Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that is unmanageable using other techniques.

Stryker's ABG™ II Modular Hip Stem is intended for cementless use only.

(K092406 pg 3/3)

Substantial Equivalence:

The ABG™ II Modular Hip Stem, referred to as ABG™ II Modular, is substantially equivalent to other commercially available hip stems in regard to intended use, design materials and operational principles as a hip prosthesis. The following devices are examples of predicate systems; Stryker Modular Hip System and Rejuvenate Monolithic Hip Size 4 Stem. Based upon the mechanical testing the ABG™ II Modular Hip Stem is substantially equivalent for its intended use to other press-fit femoral replacement hip stems currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Howmedica Osteonics Corp
% Estela Celi
325 Corporate Drive
Mahwah, New Jersey 07430

NOV - 4 2009

Re: K092406
Trade/Device Name: ABG II Modular Hip Stem
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, LZO, LPH, JDI, KWY, KWZ, KWL, LWJ
Dated: August 3, 2009
Received: August 6, 2009

Dear Ms. Celi:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson for
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): K092406 (pg 1/1)

Device Name: ABG™ II Modular Hip Stem

Indications for Use:

The indications for use of the total hip replacement prostheses include:

1) Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2) Rheumatoid arthritis
3) Correction of functional deformity;
4) Revision procedures where other treatments or devices have failed; and,
5) Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Stryker's ABG™ II Modular Hip Stem is intended for cementless use only.

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)

Joanita J for MXM

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

510(k) Number K092406