

K110807

510(k) Summary of Safety and Effectiveness

MAY 25 2011

Sponsor Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430

Contact Person Stephanie Fitts
Sr. Director, Regulatory Affairs & Regulatory Compliance
Howmedica Osteonics Corp.
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Date Prepared: March 21, 2011

Proprietary Name: ABG™ II Monolithic Hip Stem

Common Name: Hip prosthesis

Classification Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, 21 CFR §888.3353 (Product Codes MAY, LZO, MEH)

Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis, 21 CFR §888.3358 (Product Codes LPH, MBL)

Legally Marketed Device to Which Substantial Equivalence is Claimed:
ABG™ II Modular Hip Stem K092406.

Device Description:

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

The subject hip stem is a TMZF (Ti-11.5 Mo-6Zr-2Fe) alloy femoral stem with a roughened hydroxylapatite coating in the proximal region. It is intended for cementless, press-fit application and designed for use with the currently available compatible Howmedica Osteonics' femoral heads, bipolar heads, and their compatible acetabular components.

The ABG™ II Monolithic Hip Stem is a sterile, single-use device intended for use in primary and revision total hip arthroplasty to alleviate pain and restore function. The stem is designed for use with the currently available compatible Howmedica Osteonics' femoral heads and their compatible acetabular components. Head compatibility with the 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.

The ABG™ II Monolithic Hip Stem will be available in 8 sizes ranging from size 1 through 8 with one neck angle of 130°. The ABG™ II Monolithic Hip Stem anatomic stem is made with 12° of anteversion built into the proximal portion of the stem.

Indications:

The indications for use for total hip arthroplasty include:

- noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- rheumatoid arthritis;
- correction of functional deformity;
- revision procedures where other treatments or devices have failed; and,
- nonunions, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Additional indication specific to use of ABG™ II Monolithic Hip Stem with compatible Howmedica Osteonics Constrained Liners:

- When the stem is to be used with compatible Howmedica Osteonics Constrained Liners, the device is intended for use in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability.

The Stem is intended for cementless, press-fit use only and is intended for total and hemi-arthroplasty procedures.

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 hip stem to determine substantial equivalence. Non-clinical testing was provided as outlined in the FDA Guidance Document entitled “Non-clinical Information for Femoral Stem Prostheses (17 September 2007)”. Femoral neck fatigues testing and distal stem fatigues testing were conducted on the worst-case sizes determined by Finite Element Analysis. The testing demonstrated that the ABG™ II Monolithic Hip Stem is substantially equivalent to devices currently cleared for marketing.

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

Conclusion: The ABG™ II Monolithic Hip Stem is substantially equivalent to the predicate devices identified in this premarket notification.



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.
% Dr. Stephanie Fitts
325 Corporate Drive
Mahwah, NJ 07430

MAY 25 2011

Re: K110807

Trade/Device Name: ABG™ II Monolithic Total Hip Stem
Regulation Number: 21 CFR §888.3353; 21 CFR §888.3358
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis; Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis
Regulatory Class: II
Product Code: MAY, LZO, MEH; LPH, MBL
Dated: March 21, 2010
Received: March 23, 2010

Dear Dr. Fitts,

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,



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

Enclosure

Section 4: Indications for Use Statement

510(k) Number (if known): K110807

Device Name: ABG™ II Monolithic Hip Stem

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- rheumatoid arthritis;
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Additional indication specific to use of ABG™II Monolithic Hip Stem with compatible Howmedica Osteonics Constrained Liners:

When the stem is to be used with compatible Howmedica Osteonics Constrained Liners, the device is intended for use in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability.

Stryker's ABG™ II Monolithic Hip Stem is intended for cementless use only and is intended for total and hemi-arthroplasty procedures.

Prescription Use X

(Part 21 CFR 801 Subpart D)

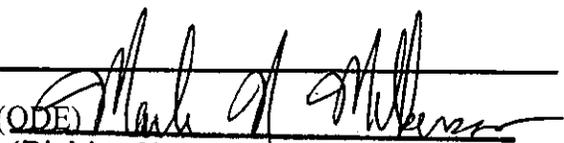
AND/OR

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)



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