K103479

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510(k) Summary

Proprietary Name: Novel Tapered Hip Stem (aka Accolade II Femoral Hip Stem)

MAR 10 2011

Common Name: Hip prosthesis

Classification Name and Reference:
Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis,
21 CFR §888.3353

Regulatory Class: Class II

System 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 LWJ – prosthesis, hip, semi-constrained, metal/polymer, uncemented
87 KWZ - prosthesis, hip, constrained, cemented or uncemented, metal/polymer
87 KWL - prosthesis, hip, hemi-, femoral, metal
87 KWY - Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
87 JDI - prosthesis, hip, semi-constrained, metal/polymer, cemented
87 LPH - prosthesis, hip, semi-constrained, metal/polymer, porous uncemented

Contact Person: Estela Celi, Regulatory Affairs Associate
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Mahwah, NJ 07430
Phone: (201) 831-6461 Fax: (201) 831-3461

Date Prepared: March 9, 2011

Legally Marketed Device to Which Substantial Equivalence is Claimed:
Accolade TMZF Hip Stem: K994366, K020572 & K023102
Restoration Modular Hip Stem: K013106

Description:
Howmedica Osteonics is introducing the Accolade II Femoral Hip Stem, a tapered non-porous coated femoral stem intended for cementless, press-fit application. The basic design of the Accolade II Femoral Hip Stem is similar to other total hip stems commercially distributed such as the Accolade TMZF Hip Stem. There are differences to the design of the subject hip stem, such as a variable medial curvature which increases with each stem size in order to facilitate press fit stability and load transmission in the proximal region of the femur. The stem geometry is designed to address variations in patient femoral morphology. The overall stem length has been reduced, compared to the Accolade TMZF hip stem, to facilitate intra-operative stem insertion.

The stem is manufactured from a Ti-6Al-4V substrate material, Commercially Pure (CP) Titanium coating and Purefix hydroxylapatite (HA) coating identical to the previously cleared 2 Piece Modular Hip Stem (K013106). The 2 Piece Modular Hip Stem (K013106) is now marketed and will be referred to throughout this submission as the Restoration Modular Hip Stem.

The Accolade II Femoral Hip Stem will be available in 12 sizes ranging from size 0 through 11 with two neck angles (127° and 132°) that provide dual head offsets. The stem is designed for use with the currently available compatible Howmedica Osteonics' femoral heads and their compatible acetabular components. All instrumentation is listed in the Surgical Protocol attached.

The Accolade II Femoral 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 subject hip stem is compatible with V40 heads, C-taper

heads when used with the V40/C-Taper Adaptor Sleeve, Universal Heads when used with the V40/Universal Adaptor Sleeve and Unitrax Heads.

Indications:
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) Nonunions, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Additional indication specific to use of Accolade II Femoral Stems with compatible Howmedica Osteonics Constrained Liners:

1. 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.

Accolade II Femoral Stems are intended for cementless use only and are intended for total and hemiarthroplasty procedures.

Technological Characteristics
The technological characteristics are basically the same as the predicates identified in the Legally Marketed Devices to which substantial equivalence is claimed with differences noted in design of the subject hip stem such as variable medial curvature, distal lateral relief and reduction in overall stem length to accommodate various surgical approaches, specifically the direct anterior approach. Stem lengths are within the range of legally marketed predicates.

Substantial Equivalence:
The Accolade II Femoral Hip Stem 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: Accolade TMZF Hip Stem and Restoration Modular Hip Stem. Based upon the mechanical testing, the Accolade II Femoral Hip Stem is substantially equivalent for its intended use to other press-fit femoral replacement hip stems currently on the market.

Summary of Non-Clinical Testing:
Non-clinical testing bench testing was provided and included Range of Motion analysis, proximal fatigue, and distal fatigue testing. All of the observed results indicate that the Accolade II Hip System is substantially equivalent to devices currently marketed. Therefore, the subject device is as safe, as effective, and performs at least as safely and effectively as legally marketed predicates identified.

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

MAR 21 2011

Howmedica Osteonics Corp.
% Ms. Estela Celi
Regulatory Affairs Associate
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K103479
Trade/Device Name: Novel Tapered 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, LWJ, KWZ, KWY, KWL, JDI, LPH
Dated: February 18, 2011
Received: February 22, 2011

Dear Ms. Celi:

This letter corrects our substantially equivalent letter of March 10, 2011.
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 (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,

for

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): K103479

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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. McKeown

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

510(k) Number K103479