510(k) Summary of Safety and Effectiveness FEB 1 2013

Proprietary Name:	Novel Fit and Fill Hip Stem (Secur-Fit Advanced)
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
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
For Information contact:	Valerie Giambanco, Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-6275 Fax: (201) 831-3275
Date Prepared:	January 8, 2013

Description:

Howmedica Osteonics is introducing the Novel Fit and Fill Hip Stem (aka Secur-Fit Advanced), a tapered non-porous coated femoral stem intended for cementless, press-fit application. The basic design of the Secur-Fit Advanced is similar to other total hip stems that have been commercially distributed such as the Accolade II, Secur-Fit and Rejuvenate Monolithic Hip Stems. The Novel Fit and Fill and the Accolade II stem are

both made from the same material combinations. The subject device is similar in design to Secur-Fit and Rejuvenate Monolithic as they are straight stems with a normalization pattern. Three dimensional simulations have shown the normalizations on the anterior and posterior aspects of the proximal end of the stem to facilitate press-fit stability and load transmission in the proximal region of the femur. These normalizations are designed to convert medial and lateral shear stresses to compressive forces, which may facilitate proximal loading.

The stem is manufactured from a Ti-6Al-4V substrate material, Commerically Pure (CP) Titanium coating and Purefix hydroxylapatite (HA) coating identical to the previously cleared Accolade II Hip Stem (K103479, K120578).

The Secur-Fit Advanced Hip Stem has a shot peened neck and includes 16 implant sizes 4-12 (nine 132° stems & seven 127° stems) that provide dual head offsets. The stem is designed only for use with compatible Howmedica Osteonics' femoral heads and acetabular components.

Intended Use:
The Secur-Fit Advanced Hip Stem is a sterile, single-use device intended for use in primary and revision total and hemi- 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:
Indications for use 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 Secur-Fit Advanced Hip 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.

Secur-Fit Advanced Hip Stems are intended for cementless use only and are intended for total and hemiarthroplasty procedures.

Substantial Equivalence:
The Secur-Fit Advanced 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 II Hip Stem, Secur-Fit HA Hip and Rejuvenate Monolithic Hip Stem. Based upon the mechanical testing, the Secur-Fit Advanced 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:
The following tests were conducted on the subject device:
1) Distal Stem Fatigue Testing in compliance with ISO 7206-4
2) Neck Fatigue Testing in compliance with ISO 7206-6

The results of the above testing verify that the new device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 1, 2013

Howmedica Osteonics Corporation
% Ms. Valerie Giambanco, MS, RAC
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K122853
Trade/Device Name: Secur-Fit Advanced
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, KWL, KWY, JDI, LPH
Dated: January 21, 2013
Received: January 23, 2013

Dear Ms. Giambanco:

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

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

Enclosure

Indications for Use

510(k) Number (if known): K122853

Device Name: Secur-Fit Advanced

Indications for Use:

Indications for use 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 Secur-Fit Advanced Hip Stems with compatible Howmedica Osteonics Constrained Liners:

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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)

Michael C. Owens

Division of Orthopedic Devices