510(k) Summary

Sponsor:	Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430
Contact Person:	Colleen Burdel Regulatory Affairs Associate t. 201-831-5969 f. 201-831-4969
Date Prepared:	November 20 , 2012
Proprietary Name:	ABG® III Monolithic Hip Stem (also known as Anato™ Hip Stem)
Common Name:	Hip prosthesis
Classification Name and Reference:	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)

AUG 16 2013

Legally Marketed Device to Which Substantial Equivalence is Claimed:

ABG® II Monolithic Hip Stem	K110807
Accolade® II Hip Stem	K103479, K120578

Device Description:

Howmedica Osteonics is introducing a monolithic, non-porous coated femoral hip prosthesis, which is intended for cementless, press-fit application. The basic design of the Anato™ Hip Stem is similar to two other commerically distributed total hip systems, which are Howmedica Osteonics' ABG® II Monolithic and Accolade® II Hip Stems.

The Anato™ and the Accolade® II stem are both made from the same material combinations. The subject device is similar in design to the ABG® II Monolithic stem as they are both anatomic stems with a 130 degree neck angle. There are normalization patterns (scales) on the anterior and posterior aspects of the proximal end of the stem to facilitate press-fit stability and load transmission. Based on 3-Dimensional simulations, these normalizations are designed to convert medial and lateral shear stresses to compressive forces, which may facilitate proximal loading.

The subject stem is manufactured from titanium (Ti-6Al-4V) alloy, commercially pure (CP) titanium coating, and PureFix® hydroxylapatite (HA) coating identical to the previously cleared Accolade® II Hip Stem.

The Anato™ Hip Stem has a shot peened neck and will be available in 8 sizes ranging from size 1 through 8 with two different neck versions (neutral and anteverted). As the stem is anatomic, there will be a right and left component for each size. The stem is designed only for

use with compatible Howmedica Osteonics' femoral heads and acetabular components.

Intended Use:
The Anato™ 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 stem is designed for use with the currently available compatible Howmedica Osteonics' V40™ 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 Adapter, 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 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 Anato™ 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 Anato™ Hip Stem is intended for cementless use only and is intended for total and hemi-arthroplasty procedures.

Summary of Technologies:
Device comparison and mechanical testing showed that the proposed device is substantially equivalent in intended use, materials and performance characteristics to the predicate devices.

Non-Clinical Testing:
The following tests were conducted:
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 devices currently cleared for marketing.

Clinical Testing:
Clinical testing was not required as a basis for substantial equivalence.

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

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

August 16, 2013

Ms. Colleen Burdel
Regulatory Affairs Associate
Howmedica Osteonics Corporation
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K123604
Trade/Device Name: ABG® II Monolithic Hip Stem (also known as Anato™ 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: MAY, LZO, MEH, LPH, MBL
Dated: July 15, 2013
Received: July 16, 2013

Dear Ms. Burdel:

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 contact 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. 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,

Erin I. Keith

For

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): K123604

Device Name: ABG® III Monolithic Hip Stem (also known as Anato™ Hip Stem)

The indications for use for total hip arthroplasty 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 fractures, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

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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.

The Anato™ 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)

Elizabeth L. Frank -S

Division of Orthopedic Devices