

SEP 13 2007

K071082

510(k) Summary of Safety and Effectiveness

Proprietary Name: Stryker Modular Hip System

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

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

For Information contact: Vivian Kelly, Senior Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430
Phone: (201) 831-5581 Fax: (201) 831-6038

Date Prepared:

September 7, 2007

Description:

Howmedica Osteonics is introducing a modular hip prosthesis. The basic design of the Stryker Modular Hip System is similar to other total hip systems commercially distributed such as the Profemur[®] Total Hip Modular Neck System, Wright Medical Technology, Inc. and other Howmedica Osteonics' hip systems such as the Secur-Fit HA Stem, the Accolade C and TMZF HA Stems and the Citation TMZF HA Stem.

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

Intended Use

The Stryker Modular Hip 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 Howmedica Osteonics acetabular components, V40 femoral heads, C-Taper Alumina heads when used with the V40/C-Taper Adaptor and the BioloX[®] Delta Universal Taper Heads and sleeves.

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 are unmanageable using other techniques.

The Stryker Modular Hip System is intended for cementless use only.

Substantial Equivalence:

The Stryker Modular Hip is substantially equivalent to other commercially available hip systems in regards to intended use, design, materials, and operational principles as a hip prosthesis. The following devices are examples of predicate systems: the Profemur[®] Total Hip Modular Neck System, Wright Medical Technology, Inc., and other Howmedica Osteonics hip stems such as the Secur-Fit HA Stem, the Accolade C and TMZF HA Stems, and the Citation TMZF HA Stem. Based upon the mechanical testing, the Stryker Modular Hip is substantially equivalent for its intended use to other press-fit femoral replacement hips currently on the market.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Howmedica Osteonics Corp.
c/o Ms. Vivian Kelly, RAC
Senior Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K071082
Trade/Device Name: Stryker Modular Hip System
Regulation Number: 21 CFR 888.3360
Regulation Name: Hip joint femoral (hemi-hip) metallic
cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: LWJ, MEH, LZO, LPH, JDI, KWZ, KWL, KWY
Dated: August 24, 2007
Received: August 27, 2007

Dear Ms. Kelly:

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 such 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); 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.

Page 2 – Ms. Vivian Kelly

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a large, stylized "M" and "N".

Mark N. Melkerson

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071082

Device Name: Stryker Modular Hip System

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.

The Stryker Modular Hip System 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)

Barbara Fouchard
(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K071082