K082892 (pg 1/3)

510(k) Summary of Safety and Effectiveness

DEC 29 2008

Propritery Name:	**Rejuvenate Monolithic 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 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

K082892 (pg 2/3)

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

For Information contact: Denise Daugert, Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430
Phone: (201) 831-5413 Fax: (201) 831-6038

Date Prepared: September 29, 2008

Description:
Howmedica Osteonics is introducing a monolithic hip prosthesis. The basic design of the Rejuvenate Monolithic Hip System is similar to other total hip systems commercially distributed such as the Secur-Fit HA Stem and the Accolade TMZF HA Stems.

The subject hip is composed of a monolithic stem 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 Rejuvenate 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. 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.
6) Stryker's Rejuvenate Hip System is intended for cementless use only.

Substantial Equivalence:

The Rejuvenate Monolithic Hip Stem 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 Secur-Fit HA Stem and the Accolade TMZF HA Stems. Based upon the mechanical testing, the Rejuvenate Monolithic Hip Stem is substantially equivalent for its intended use to other press-fit femoral hip replacement currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Howmedica Osteonics Corp.
% Ms. Denise Daugert
Regulatory Affairs Specialist
325 Corporate Dr.
Mahwah, New Jersey 07430

DEC 29 2008

Re: K082892
Trade/Device Name: Rejuvenate Monolithic Hip System
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, LPH, JDI, KWY, KWZ, KWL, LWJ
Dated: September 29, 2008
Received: September 30, 2008

Dear Ms. Daugert:

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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,

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): K082892 (ps 1/17)

Device Name: Rejuvenate Monolithic Stem

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.
6) Stryker's Rejuvenate 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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082892