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510(k) Summary of Safety and Effectiveness for the Modifications to the Restoration® Modular System

Proprietary Name: Restoration® Modular System

Name: Femoral Hip Prosthesis

Regulatory Class: Class II

Classification Names and References:

Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, 21 CFR §888.3353,

Prosthesis, hip, semi-constrained, metal/polymer, uncemented, 21 CFR §888.3350

Hip joint metal/polymer semi-constrained cemented prosthesis, 21 CFR §888.3350

Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, 21 CFR §888.3358

Prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calicum-phosphate

Hip joint metal/polymer constrained cemented or uncemented prosthesis, 21 CFR §888.3310

Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis, 21 CFR §888.3390

Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis, 21 CFR §888.3360

Product Codes: 87 LZO, 87 LWJ, 87 JDI, 87 LPH, 87 MEH, 87 KWZ, 87 KWY, and 87 KWL

Contact Information: Vivian Kelly, Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430
Phone: (201) 831-5467
Fax: (201) 831-6038

Date Prepared: July 27, 2004

Device Description:
The Restoration® Modular Hip System is a modular hip system comprise of different proximal body styles and three distal stem designs, which are affixed with the use of a locking bolt. These individual components are assembled by the surgeon in the operating room or in situ to allow independent sizing of the proximal body and distal stem to better fit the patient. This submission modifies the existing 19mm Cone Body

and adds a new style of proximal body called the MT3 body for use with the previously cleared distal stem components.

Intended Use:
The Restoration® Modular System is intended for for primary or revision total hip arthroplasty, as well as in the presence of severe proximal bone loss. These femoral stems are designed to be press fit into the proximal femur. Examples of specific indications for use of the Restoration® Modular System include, non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis, rheumatoid arthritis, correction of functional deformity, revision procedures where other treatments or devices have failed; and treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Substantial Equivalence:
The features of the new components are substantially equivalent to the predicate devices based on similarities in intended use, materials and design. Mechanical testing demonstrates substantial equivalence of the new components to the predicate devices in regards to mechanical strength. In addition, the intended use, material, manufacturing methods, packaging, and sterilization of the predicate and new components are identical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 5 2004

Ms. Vivian Kelly
Regulatory Affairs Specialist
Stryker Howmedica Osteonics
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K040734

Trade/Device Name:	Restoration Modular System: Addition of the MT3 body; Modification to the 19mm Cone Body
Regulation Number:	21CFR 888.3353; 21CFR 888.3350; 21 CFR 888.3358; 21 CFR 888.3310; 21CFR 888.3390; 21CFR 888.3360
Regulation Name:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis; Hip joint metal/polymer semi-constrained cemented prosthesis; Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis; Hip joint metal/polymer constrained cemented or uncemented prosthesis; Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis; and Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis

Regulatory Class: II
Product Code: LZO, LWJ, JDI, LPH, KWZ, KWY, KWL, MEH
Dated: August 2, 2004
Received: August 4, 2004

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.

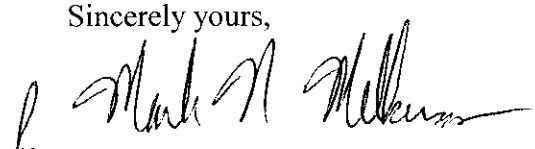
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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.

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 (301) 594-4659. 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 its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia Witten, Ph.D., M.D.
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): K040734

Device Name: Restoration® Modular System

Indications For Use:

The Restoration® Modular System is intended for primary or revision total hip arthroplasty, as well as in the presence of severe proximal bone loss. These femoral stems are designed to be press fit into the proximal femur. Examples of specific indications for use of the Restoration® Modular System include:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis,
- Rheumatoid arthritis,
- Correction of functional deformity,
- Revision procedures where other treatments or devices have failed, and
- Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milleras

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

510(k) Number K040734