K042774

JAN 2 1 2005

BIOMET

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: Mallory-Head® Modular Calcar Stems with Interlocking Slots

Common Name: Common or Usual Name: Total hip femoral component

Classification Name:
1. Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR 888.3310)
2. Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis (21 CFR 888.3320)
3. Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis (21 CFR 888.3330)
4. Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3350)
5. Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353)
6. Hip joint metal/polmer/metal semi-constrained, porous-coated, uncemented prosthesis (21 C.F.R. 888.3358)
7. Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (21 CFR 888.3390)

Product Codes: KWZ, JDL, KWA, JDI, LZO, LPH, KWY

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
Interlocking Hip Stems - K990830
Mallory-Head® Modular Calcar with and without HA - K031693

Device Description: The Mallory-Head® Modular Calcar System consists of a variety of proximal metaphyseal segments and distal stems. This 510(k) was for a distal stem that has three medial/lateral slots located in the distal half of the device designed for cross screw placement. The proximal bodies and distal stems of the

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
574.267.6639 ■ FAX
574.267.8137 ■ E-MAIL
biomet@biomet.com

Mallory-Head® Modular Calcar System are joined by means of a Morse locking taper similar to that used to attach the modular head components to most hip stems. The cross-screws are available in lengths of 25mm to 60mm and 5mm diameters.

Intended Use: Mallory-Head Modular Calcar Stems with Interlocking Slots are indicated for non-cemented application in cases of revision, trauma, fracture, oncology or other situations where severe proximal bone loss may compromise the fixation and stability of a standard type hip replacement prosthesis.

Summary of Technologies: The Mallory-Head® Modular Distal Stems with Interlocking Slots have similar characteristics to the predicate devices.

Non-Clinical Testing: Mechanical testing has been conducted to demonstrate the ability of the screws to survive physiological loading.

Clinical Testing: None provided

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K042774
Trade/Device Name: Mallory-Head® Modular Calcar Stems with Interlocking Slots
Regulation Number: 21 CFR 888.3320; 21CFR 888.3330; 21 CFR 888.3358; 21 CFR 888.3353; 21 CFR 888.3310; 21 CFR 888.3350; 21 CFR 888.3390
Regulation Name: Hip joint metal/metal semi-constrained, with a cemented acetabular Component, prosthesis; Hip joint metal/metal semi-constrained with an uncemented acetabular component, prosthesis Hip joint metal/ polymer/ metal semi-constrained porous-coated uncemented prosthesis; Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prothesis; Hip joint metal/polymer constrained cemented or uncemented prosthesis; Hip joint metal / polymer semi-constrained cemented prosthesis; Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis;
Regulatory Class: III
Product Code: JDL, KWA, LPH, LZO, KWZ, JDI, and KWY
Dated: December 17, 2004
Received: December 20, 2004

Dear Ms. Beres:

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 (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 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 M. 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): K042774

Device Name: Mallory-Head® Modular Calcar Stems with Interlocking Slots

Indications For Use:

Mallory-Head® Modular Calcar Stems with Interlocking Slots are indicated for non-cemented application in cases of revision, trauma, fracture, oncology or other situations where severe proximal bone loss may compromise the fixation and stability of a standard type hip replacement prosthesis.

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 Milhous

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

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