AUG - 6 2003

K031693

BIOMET
ORTHOPEDICS, INC.

Summary of Safety and Effectiveness

Applicant/Sponsor: Biomet Orthopedics, Inc.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: Mallory-Head® Modular Calcar Femoral Component with and without HA

Common Name: Total hip femoral component

Classification Name: Hip joint metal/polymer/metal semi-constrained, porous coated, uncemented prosthesis (21 CFR 888.3358)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
Mallory-Head Modular Calcar Replacement Components, 510(k) K945115
Mallory-Head Modular Calcar Total Hip with Roller- Hardened/Machined Tapers, 510(k) K000335
The Reach® Femoral Component, 510(k) K000760
Mallory-Head Modular Calcar (100% porous stems), 510(k) K001660
The HA Modular Reach® Femoral Component, 510(k) K022463

Device Description: : Each stem consists of two separate parts, a proximal metaphyseal segment and a distal stem. A variety of stem lengths and proximal segment sizes allow the surgeon to "construct" the proper sized implant while in surgery. All pieces are interchangeable. The device utilizes a modular femoral head taper fit on to the stem at the time of surgery.

The proximal segment is designed to replace the proximal portion of the femur in cases of severe bone loss. The device is porous coated. The proximal components are available in 5 resection levels and 7 widths.

A hole through the proximal component gives the surgeon the option of using a trochanter plate and trochanter bolt or a trochanter claw. This assembly will allow the greater trochanter to be compressed against the prosthesis for enhanced fixation and proximal stability.

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Distal stems are available in six lengths, 165mm, 200mm, 220mm, 240mm, 250mm and 300mm. Stems are available with 40%, 80% or 100% of the stem porous coated, as well as a non-coated, splined configuration. Since the stems are modular, left and right components are not necessary.

The proximal and distal segments are joined by means of a Morse locking taper similar to that used to attach the modular head components to most hip stems. Additional fixation is achieved through a locking screw inserted through the driving platform on the metaphyseal component and engaging with the stem taper.

Intended Use: Non-cemented application in cases of:

1) Noninflamatory degenerative joint disease including osteoarthritis and avascular necrosis
2) Rheumatoid arthritis
3) Correction of functional deformity
4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
5) Revision of previously failed total hip arthroplasty

Summary of Technologies: The materials, design and processing of the devices are identical to or similar to the predicates.

Non-Clinical Testing: Engineering analysis, finite Element Analysis and mechanical testing were provided.

Clinical Testing: None provided.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 2003

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, IN 46581-0587

Re: K031693
Trade/Device Name: Mallory-Head Modular Calcar with and without HA
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint/metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH
Dated: July 18, 2003
Received: July 22, 2003

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 (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,

Miriam C. Provost

for 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

510(k) Number (if known): K031693

Device Name: Mallory/Head Modular Calcar with and without HA

Indications For Use:

Cemented and non-cemented total joint replacement in cases of:

1) Noninflamatory degenerative joint disease including osteoarthritis and avascular necrosis
2) Rheumatoid arthritis
3) Correction of functional deformity
4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
5) Revision of previously failed total hip arthroplasty

Miriam C. Provost

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

510(k) Number K031693

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)