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K000335

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SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Biomet, Inc.

Manufacturer: Biomet Manufacturing, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, Indiana 46581-0587

Proprietary Name: Mallory-Head Modular Calcar Total Hip

Common or Usual Name: Metallic total hip system

Classification Name: Prosthesis, hip, semi-constrained, metal/polymer, porous uncemented (888.3358);
Prosthesis, hip, semi-constrained, metal/polymer, Cemented (888.3350)

Device Classification: Class II

Device Product Code: 87LPH; 87JDI

Device Description: The predicate Mallory-Head Modular Calcar was originally cleared in K945115 for non-cemented use. The distal stem has been modified by applying a roll-hardened/machined process to the male portion of the Morse locking taper that joins the proximal and distal portions of the stem. The predicate and modified devices are made of the same and have the same surface finishes and indications for use as well as the same lengths and configurations. These modified distal stems are interchangeable with all of Biomet's modular hip systems. As with the predicate, the proximal body and the distal stem are joined by means of a Morse locking taper.

Indications For Use: 1) Noninflammatory 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 using other techniques; 5) revision of previously failed total hip arthroplasty due to recurrent dislocations.

Potential Risks:

1) Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant.
2) Early or late postoperative, infection, and allergic reaction.

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3) Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
4) Loosening or migration of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption, excessive activity.
5) Periarticular calcification or osseification, with or without impediment of joint mobility.
6) Inadequate range of motion due to improper selection or positioning of components.
7) Undesirable shortening of limb.
8) Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity can also contribute to these conditions.
9) Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
10) Fretting and crevice corrosion can occur at interfaces between components.
11) Wear and/or deformation of articulating surfaces.
12) Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing or inadequate reattachment.
13) Problems of the knee or ankle of the affected limb or contralateral limb aggravated by leg length discrepancy, too much femoral medialization or muscle deficiencies.
14) Postoperative bone fracture and pain.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 25 2000

Mr. Fred McClure
Regulatory Specialist
Biomet Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K000335
Trade Name: Mallory-Head Modular Calcar Total Hip with Roller-Hardened/Machined Tapers
Regulatory Class: II
Product Code: LPH and JDI
Dated: January 27, 2000
Received: February 3, 2000

Dear Mr. McClure:

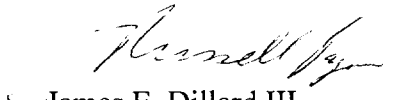
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4559. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known) : K000335

Device Name: Mallory-Head Modular Calcar Total Hip

Indications For Use: 1) Noninflammatory 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 using other techniques; 5) revision of previously failed total hip arthroplasty due to recurrent dislocations.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000335

Prescription Use X
(Per 21 CFR 801.109)

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