MAR 1 5 2000

K000538

SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor:

(Mailing Address) Biomet, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, IN 46581-0587

(Shipping Address) Biomet, Inc.
56 East Bell Drive
Warsaw, IN 46582

Contact: Dalene T. Binkley
Telephone: (219) 372-1612

Trade Name: Mallory/Head Lateralized Press-Fit Femoral

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

Device Description: This series of press-fit stems comes in sizes from 9-14mm in one millimeter increments. The stems are identical to the standard offset Mallory/Head Press-Fit Femorals from the collar down. Overall lengths of the stems are also identical to the predicate series of stems. The difference in the two series lies only in the horizontal offsets and neck angle. The offset is increased from the center of a standard head to the center of the stem and also the post geometry is altered from a neck angle of 130 degrees as opposed to the predicate 135 degrees.

Indications for Use:

1) Non-inflammatory 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 throchanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

Potential Risks: The potential risks associated with this device are the same as with any joint replacement device. These include, but not limited to:

Reaction to bone cement	Blood vessel damage	Bone fracture
Deformity of the joint	Soft tissue imbalance	Infection
Cardiovascular diseases	Delayed would healing	Hematoma
Fracture of the cement	Metal sensitivity	Dislocation
Implant loosening/Migration	Fracture of the components	Excessive wear
Tissue growth failure	Nerve damage	

Modifications were made to the Mallory/Head Press-Fit Femoral to produce the Mallory/Head Lateralized Press-Fit Femoral.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 5 2000

Ms. Dalene T. Binkley
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Airport Industrial Park
Warsaw, Indiana 46581-0587

Re: K000538
Trade Name: Mallory/Head Lateralized Press-Fit Femoral
Regulatory Class: II
Product Code: LPH
Dated: February 16, 2000
Received: February 17, 2000

Dear Ms. Binkley:

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 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 control provisions of the Act. The general control 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 requirement, 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) 594-4659. 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" (21 CFR 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 at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K000538

DEVICE NAME: Mallory/Head Lateralized Press-Fit Femoral

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 throchanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

Standard surgical and rehabilitative procedures are indicted with this device.

This device is for use with bone cement.

NRO for CMW

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000538

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)