

FEB 4 2000

K 994007  
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## SUMMARY OF SAFETY AND EFFECTIVENESS

**SPONSOR:** Biomet, Inc.  
Airport Industrial Park  
P. O. Box 587  
Warsaw IN 46580 -0587

**CONTACT PERSON:** Tina Lakin  
(219) 267-6639 ext. 1816

**DEVICE NAME:** Mallory/ Head Smooth Femoral Stem

**CLASSIFICATION NAME:** Hip Femoral Component Prosthesis, Cemented, Metal  
(CFR 888.3360)

**INDICATIONS FOR USE:** Mallory/ Head Smooth femoral stem is indicated for use in:

- 1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- 2) Rheumatoid arthritis
- 3) Correction of functional deformity
- 4) Revision procedures where other treatment or devices have failed
- 5) Treatment of nonunions, which are femoral neck and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

**DEVICE DESCRIPTION:** The Mallory/Head Smooth femoral components are composed of Co-Cr-Mo alloy conforming to ASTM F-799 standards. The Mallory/Head Smooth is to be used with bone cement. A progressive increase in cross-sectional dimensions and overall length is seen throughout the range of sizes (size 1 -5). The straight stem design eliminates the need for left and right configurations.

The most defining feature of this series is the surface geometry and finish of the stem body. The finish is sisal buff in one direction (proximal to distal) around the entire stem with a roughness ( $R_a$ ) value not less than 24 microinches. The surface is void of ledges, grooves, and collars. This smooth design will allow minute amounts of subsidence over an extended period of time. The smooth stem is used with the centralizer/sinker set so that the stem continues to remain tightly wedged in place rather than loosening progressively over time.

The centralizer/sinker set consists of two polymethylmethacrylate (PMMA) pieces. The sinker fits on the distal tip of the stem and creates a 2-3 mm (in length) void in the cement mantle. Without this void, distal to the tip of the stem,

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small amounts of subsidence would cause undesirable point loads in the cement. The centralizer is designed to fit on the central one-third of the stem and to provide a cement mantle of uniform thickness around the stem.

The Mallory/Head Smooth Femoral Component can be used with any Biomet modular head with a Type 1 taper, such as: Cobalt Chrome modular heads, Zirconia modular heads or an endoprosthesis head. Zirconia ceramic heads have been previously cleared in 510(k)'s: K905687, K913420, K925345, K943586, K964431, K991708. For metallic heads the surface of the bore of the head was measured to have a roughness ( $R_a$ ) value of 34 microinches. The articulating surface roughness ( $R_a$ ) value was found to be 5.6. The ceramic heads have a surface roughness of  $R_a < 0.2$  microns on the articulating surface and 0.4 – 0.8 microns in the head bore. Any commercially available acetabular component may be used with the Mallory/ Head Smooth femoral component.

**POTENTIAL RISKS:** The potential risks with this device are the same with any other joint replacement device. These include, but are not limited to:

Fracture of component	Bone fracture
Cardiovascular disorders	Hematoma
Implant loosening/migration	Blood vessel damage
Soft tissue loosening	Nerve damage
Deformity of the joint	Excessive wear
Tissue growth failure	Infection
Delayed wound healing	Dislocation
Metal sensitivity	

**SUBSTANTIAL EQUIVALENCE:** The Mallory/Head Smooth femoral component is similar to most femoral components on the market today in terms of overall intended function and design. Direct comparison was made with the following predicates:

- Biomet Cobalt-Chrome Femoral Component (Mallory/Head Cemented Femoral) – (Biomet Inc. – 510(k) K911684)
- Rx 90 Hip System – (Biomet Inc. – 510(k) K942028)
- Color Buffed Cemented Femoral – (Biomet Inc. – 510(k) K992903)



FEB 4 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Tina Lakin  
Regulatory Specialist  
Biomet, Inc.  
P.O. Box 587  
Airport Industrial Park  
Warsaw, Indiana 46581-0587

Re: K994007  
Trade Name: Mallory/Head Smooth Femoral Stem  
Regulatory Class: II  
Product Code: JDI  
Dated: November 23, 1999  
Received: November 24, 1999

Dear Ms. Lakin:

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 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 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

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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,



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

Enclosure

510(k) NUMBER (IF KNOWN): K994007

DEVICE NAME: Mallory/ Head Smooth femoral component

INDICATIONS FOR USE:

The Mallory/ Head Smooth femoral component is indicated for:

- 1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- 2) Rheumatoid arthritis
- 3) Correction of functional deformity
- 4) Revision procedures where other treatment or devices have failed
- 5) Treatment of nonunions, which are femoral neck and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

This device is for use with bone cement.

NRO for JSD  
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 (Division Sign-Off)  
 Division of **General Restorative Devices**  
 510(k) Number K994007

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes  
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use No  
(Optional Format 1-2-96)

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