K993438

MAY 1 8 2000

SUMMARY OF SAFETY AND EFFECTIVENESS

SPONSOR:	Biomet, Inc. P.O. Box 587 Airport Industrial Park Warsaw, Indiana 46581-0587
CONTANT PERSON:	Michelle L. McKinley
DEVICE NAME:	Metal on Metal Acetabular System
CLASSIFICATION NAME:	Prosthesis, Hip, Semi-constrained (Metal Uncemented Acetabular Component)

INTENDED USE:

The Metal on Metal Acetabular System is indic. ted for used in patients requiring total hip replacement due to the following:

a.) Non-inflammatory degenerative joint disease including avascular necrosis, diastrophic variant, fracture of the pelvis, fused hip, leg perthes, osteoarthritis, slipped capital epiphysis, subcapital fractures, and traumatic arthritis
b.) Rheumatoid arthritis
c.) Correction of functional deformity
d.) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
e.) Revision of previously failed total hip arthroplasty.

DEVICE DESCRIPTION:

The Metal on Metal Acetabular System consists of a titanium outer shell with a cobalt chromium metallic liner, which articulates with a cobalt chromium modular head. Based on mechanical testing, it has been shown that the Metal on Metal Acetabular System exhibits decreased wear compared to the wear observed in the traditional polyethylene and metal acetabular systems.

Acetabular Shell

The acetabular shells that will initially be available in two designs, the Mallory Head Radial and the Universal Acetabular Component. Both designs are modular two-piece systems consisting of a modular cobalt chromium (Co-Cr-Mo) liner and a porous coated titanium shell. Hemispherical shape of both outer shells closes matches the natural acetabulum, which leads to minimal bone removal in preparation for implantation. The two acetabular shell designs are available with holes or as a solid dome. If necessary, the

shell with holes allows the use of 6.5 mm dome and the 5.0 mm rim screws for optional supplemental fixation. The solid shell configuration without dome holes increases the surface area of the porous plasma spray coating. The Mallory Head acetabular shell features four fins, which aid in preventing rotation.

The outer surface of the shell is covered with a porous coating of titanium alloy (Ti-6Al-4V) powder conforming to ASTM-F136, which ensures immediate component fixation and maximum bone-to-implant contact. The plasma sprayed surface consists of particles which are bonded together to form a random pattern with interconnecting pores.

Acetabular Liner

The metallic cobalt chromium bearing liner fits into the outer shell by means of a taper similar to the taper used for the attachment of the modular head. The locking mechanism consists of a three degree taper with a maximum engagement of 0.075 inches. The surface roughness of the articulating surface averages 0.17 micro-inches R_a. The sphericity of the liner components has an average Peak to Valley deviation of 59.8024 micro-inches. This is less than half the allowable deviation set forth in the ISO standard for modular head sphericity.

Modular Femoral Head

The Metal on Metal Acetabular System utilizes a 28mm cobalt chromium (Co-Cr-Mo) modular femoral head with seven neck lengths (-6mm to +12mm). Each modular head has a four degree angle included in the bore with a surface roughness of 34 micro-inches. The articulating surface is highly polished with a surface roughness of 0.43 micro-inches.

The modular heads may be used in conjunction with any of Biomet's commercially available femoral components. At the time of surgery, the modular head is assembled with a femoral stem.

POTENTIAL RISKS:

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

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

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SUBSTANTIAL EQUIVALENCE:

The Metal on Metal Acetabular System is similar to previously marketed devices. Direct comparison was made with the following predicate devices:

Mallory Head Finned Acetabular Cup
Universal Acetabular Cup
Biomet Co-Cr Femoral Components
Sulzer's Inter-Op Metasul

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 8 2000

Ms. Michelle L. McKinley
Regulatory Specialist
Biomet, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K993438/S1
Trade Name: Metal on Metal Acetabular Component
Regulatory Class: III
Product Code: KWA
Dated: February 18, 2000
Received: February 22, 2000

Dear Ms. McKinley:

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,

for Celia M. Whitten, 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: K993438
Device Name: Metal on Metal Acetabular System

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(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 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993438