K04 2037

OCT 1 - 2004

BIOMET INC

510(k) Summary of Safety and Effectiveness

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Kacy Arnold
Regulatory Specialist

Proprietary Name: M^2a™ Magnum™ System

Common Name: Metallic Acetabular Articulation

Classification Name: Hip joint metal/metal semi-constrained, with uncemented acetabular component prosthesis (888.3330)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

The M^2a™ Magnum™ System is substantially equivalent to:

- K011110 M2a™ Acetabular System 38mm *(Biomet)*
- K984028 Bio-Moore Endo Heads *(Biomet)*
- K002106 New Bio-Moore Endo Head, Taper Adapter *(Biomet)*
- K031963 Conserve® Plus Spiked Shell and Conserve® Total 56mm Femoral Head *(Wright Medical)*
- K021249 Metal Transcend® Articulation System (Wright Medical)

Device Description:

The M^2a™ Magnum™ System consists of a CoCrMo monolithic acetabular cup, which articulates with a CoCrMo modular head. The smaller femoral heads, sizes 38mm and 40mm, are a one-piece design with neck length variations ranging from –6mm to +12mm. The larger femoral heads, sizes 42mm to 60mm, are a modular design with neck length variations ranging from -6mm to +9mm, achieved through the use of a titanium adapter assembled with the modular head component at the time of surgery. The femoral heads may be used in conjunction with any of Biomet's commercially available Type I taper femoral component.

Summary of Technologies: The M^2a™ Magnum™ Hip System technological characteristics (material and design) are similar to predicate devices.

Non-Clinical Testing: Mechanical testing was performed to establish substantial equivalence to the predicate devices.

Clinical Testing: Clinical testing was not used to establish substantial equivalence to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 - 2004

Ms. Kacy Arnold, RN, MBA
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, IN 46581-0587

Re: K042037
Trade Name: M^{2}a™ Magnum™ System
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with uncemented acetabular component prosthesis
Regulatory Class: III
Product Code: KWA
Dated: July 28, 2004
Received: July 29, 2004

Dear Ms. Arnold:

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,

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

Enclosure

Indications for Use

510(k) Number (if known): K042037

Device Name: M²a™ Magnum™ Hip System

Indications For Use:

The M²a™ Magnum™ System is indicated for use in patients requiring total hip replacement due to the following:

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

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milhous

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

510(k) Number K042037