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BIOMET ORTHOPEDICS, INC.

JUL 27 2006

510(k) Summary

Preparation Date: May 19, 2006

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Becky Earl, Regulatory Specialist

Proprietary Name: M2a Magnum™ 12/14 Taper Inserts and One-Piece Modular Heads

Common Name: metal-on-metal inserts and modular heads

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

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: M2a Magnum™ Systems—K042037 (Biomet, Inc.); ASR™ Modular Acetabular Cup System—K040627 (DePuy Orthopaedics, Inc.), and TaperLoc® 12/14 Taper Femoral Components—K043537 (Biomet, Inc.).

Device Description: The M2a Magnum™ 12/14 Taper Inserts and One-Piece Modular Heads are designed for use with the TaperLoc® 12/14 taper femoral components and the articulating heads and shells of the M2a Magnum™ Sytem (K043537) for uncemented applications.

There are two sets of taper inserts, each providing neck offsets from –6mm to +9mm. The first set has a smaller diameter and mates with modular head sizes 42mm to 50mm. The second set of taper inserts has a larger outer diameter and mates with modular head sizes 52mm through 60mm. The one-piece 12/14 modular head sizes will include 38mm and 40mm outer diameters. Available neck offsets will range from –6mm to +9mm.

Intended Use:
The M2a Magnum™ 12/14 Taper Inserts and One-Piece Modular Heads are intended for use in patients requiring total hip replacement due to the following:

1. 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.
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 by other techniques.
5. Revision of previously failed total hip arthroplasty.

Summary of Technologies: The technological characteristics (materials, design, sizing, articulating surface, indications) of the M2a Magnum™ 12/14 Taper Inserts and One-Piece Modular Heads are similar or identical to the predicate devices.

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510(k) Summary: M2a Magnum™ 12/14 Taper Inserts and One-Piece Modular Heads
Biomet Manufacturing Corp.

Non-Clinical Testing: Non-clinical laboratory testing had been previously performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2006

Biomet Manufacturing Corp.
% Ms. Becky Earl
Regulatory Specialist
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K061423
Trade/Device Name: M2a Magnum™ 12/14 Taper Inserts and One--Piece Modular Heads
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component prosthesis
Regulatory Class: Class III
Product Code: KWA
Dated: May 22, 2006
Received: May 23, 2006

Dear Ms. Earl:

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

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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
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): K061423

Device Name: M2a Magnum™ 12/14 Taper Inserts and One-Piece Modular Heads

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Prescription Use ___X___ AND/OR Over-The-Counter Use __NO__
(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)

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

510(k) Number K061423