1 of 1

K042321

JAN 2 8 2005

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corporation
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581-0587

Contact Person: Kacy Arnold, RN, MBA
Regulatory Affairs Specialist
Telephone: 574-267-6639
Fax: 574-372-1683

Proprietary Name: Mosaic™ Non-modular Proximal Body and EAS Offset Modular Humeral Head

Common Name: total shoulder replacement components

Classification Name:
1) Shoulder joint metal/polymer non-constrained cemented prosthesis (888.3650)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
- K030710: Bio-Modular® Extended Articular Surface (EAS) Humeral Head (Biomet)
- K032895: Bi-Angular® Humeral Head (Biomet)
- K033280: Mosaic™ Proximal Humeral Replacement System (Biomet)
- K992899: Bio-Modular® Offset Humeral Head (Biomet)

Device Description: The Mosaic™ components are made of Co-Cr-Mo per ASTM F 75 and are available in a non-modular proximal body and an EAS offset modular design. Both designs are used to articulate on the natural glenoid bone surface or with cleared glenoid components.

Indications for Use: The Mosaic™ Non-modular Proximal Body and EAS Offset Modular Humeral Heads are for use in primary and revision shoulder joint replacement procedures in cases of:
- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Revision where other devices or treatments have failed
- Correction of functional deformity
- Treatment of acute or chronic fractures with humeral epicondyle (elbow) involvement or humeral head (shoulder), which are unmanageable using other treatment methods
- Oncology applications

Summary of Technologies: Mosaic™ Non-modular Proximal Body and Extended Articulating Surface (EAS) Offset Modular Humeral Heads is identical in materials and processing as the predicate device.

Non-Clinical Testing: Non-clinical testing demonstrated substantial equivalence between this device and the predicate devices.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 8 2005

Kacy Arnold
Regulatory Affairs Specialist
Biomet Manufacturing Corporation
56 East Bell Drive
Warsaw, IN 46581

Re: K042321
Device Name: Mosaic Non Modular Proximal Body and EAS Offset Modular Humeral head
Regulation Number: 21 CFR 888.3650
Regulation Name: Shoulder joint metal/ polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWT
Dated: 1/17/05
Received: 1/18/05

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.

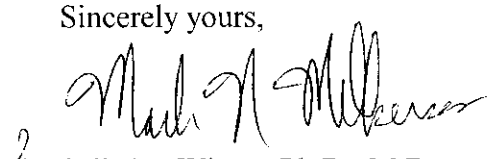
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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): K042321

Device Name: **Mosaic™ Non-modular Proximal Body and EAS Offset Modular Humeral Heads**

Indications For Use:

The Mosaic™ Non-modular Proximal Body and EAS Offset Modular Humeral Heads are for use in primary and revision shoulder joint replacement procedures in cases of:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Revision where other devices or treatments have failed
- Correction of functional deformity
- Treatment of acute or chronic fractures with humeral epicondyle (elbow) involvement or humeral head (shoulder), which are unmanageable using other treatment methods
- Oncology applications

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. Milleson

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

510(k) Number K042321