K040610

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BIOMET

JUN 0 4 2004

**510(k) Summary**

**Applicant/Sponsor:** Biomet Manufacturing Corp.

**Contact Person:** Gary Baker
Regulatory Specialist

**Proprietary Name:** Versa-Dial™ Humeral Head Prosthesis

**Common Name:** Shoulder Prosthesis

**Classification Name:**
Prosthesis, Shoulder, Non-Constrained, Metal/Polymer Cemented (21 CFR §888.3650).
Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer, Cemented (21 CFR §888.3660).
Shoulder Joint, Metal/Polymer/Metal, Non-Constrained or Semi-Constrained, Porous Coated, Uncemented Prosthesis (21 CFR §888.3670).
Shoulder Joint, Humeral, (Hemi-Shoulder), Metallic, Uncemented Prosthesis (21 CFR §888.3690).

**Legally Marketed Devices To Which Substantial Equivalence Is Claimed:**

1. Comprehensive Humeral Fracture System - Biomet Inc. (K023063)
2. Bio-Modular® Shoulder System (K030710)

**Device Description:** The Versa-Dial™ Humeral Head Prosthesis is a metallic humeral head designed to function as the articulating surface component of the Comprehensive Humeral Fracture Stem (K023063) for either cemented or uncemented (press-fit) use, and incorporates the glenoid components of the Bio-Modular® Shoulder System (K030710) that are either all polyethylene for cemented use or metal backed for uncemented (biological fixation with optional screw fixation) use. The Versa-Dial™ heads and taper adapter are manufactured of Co-Cr-Mo alloy conforming to ASTM F 75.

**Indications for Use:** 1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis

2) Rheumatoid arthritis

3) Revision where other devices or treatments have failed



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4) Correction of functional deformity

5) Fractures of the proximal humerus, where other methods of treatment are deemed inadequate.

6) Difficult clinical management problems, including cuff arthropathy, where other methods of treatment may not be suitable or may be inadequate.

**Summary of Technologies:** The Versa-Dial™ Humeral Head Prosthesis is similar to or identical in terms of material, function, labeling, and sizing to the predicate Bio-Modular® Shoulder System (K030710), and the Comprehensive Humeral Fracture System (K023063).

**Non-Clinical Testing:**Mechanical testing was performed on the Versa-Dial™ Humeral Head Prosthesis. The testing indicated that the Versa-Dial™ Humeral Head Prosthesis is substantially equivalent to the predicate device.

**Clinical Testing:** Clinical testing was not required for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 0 4 2004

Mr. Gary Baker
Regulatory Specialist
Biomet Manufacturing Corp.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K040610
Trade/Device Name: Versa-Dial™ Humeral Head Prosthesis
Regulation Number: 21 CFR 888.3650, 888.3660, 888.3670, 888.3690
Regulation Name: Shoulder joint, metal/polymer, non-constrained, cemented prosthesis; Shoulder joint, metal/polymer, semi-constrained, cemented prosthesis; Shoulder joint, metal/polymer/metal, non-constrained or semi-constrained, porous-coated uncemented prosthesis; and Shoulder joint, humeral (hemi-shoulder), metallic, uncemented prosthesis
Regulatory Class: II
Product Code: KWT, KWS, MBF, and HSD
Dated: March 5, 2004
Received: March 8, 2004

Dear Mr. Baker:

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.

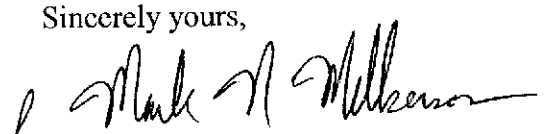
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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

**Statement of Indications For Use**

510(k) Number (IF KNOWN): K040610

Device Name: Versa-Dial™ Humeral Head

Indications for Use:

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis

2) Rheumatoid arthritis

3) Revision where other devices or treatments have failed

4) Correction of functional deformity

5) Fractures of the proximal humerus, where other methods of treatment are deemed inadequate.

6) Difficult clinical management problems, including cuff tear arthropathy, where other methods of treatment may not be suitable or may be inadequate.

The Versa-Dial™ Humeral Head Prosthesis is intended for use with the Comprehensive Humeral Fracture Stem for either cemented or uncemented (press-fit) use.

The Versa-Dial™ Humeral Head Prosthesis is intended for use with the glenoid components of the Bio-Modular® Shoulder System, either all polyethylene for cemented use or metal backed for uncemented (biological fixation with optional screw fixation) use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milhous

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



**510(k) Number** K040610