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510(k) Summary

Preparation Date: June 8, 2006

Applicant/Sponsor: Biomet Manufacturing Corp. JUN 12 2006

Contact Person: Susan Alexander

Proprietary Name: Versa-Dial™ Humeral Head Prosthesis

Common Name: Shoulder Prosthesis

Classification Name:
- Shoulder joint metal/polymer non-constrained cemented prosthesis (21 CFR §888.3650)
- Shoulder joint metal/polymer semi-constrained cemented prosthesis (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:
- Versa-Dial™ Humeral Head Prosthesis; Biomet Manufacturing Corp. (K040610)
- Bio-Modular® Shoulder System; Biomet Orthopedics, Inc. (K030710)
- Absolute® Bi-Polar Shoulder System; Biomet Manufacturing Corp. (K002998)

Device Description: The Versa-Dial™ Humeral Head Prosthesis consists of a series of various-sized modular humeral heads with variable offset between 0.5mm and 4.5 mm. Each modular head consists of a head and a taper adaptor. The taper adaptor is impacted into the head in a certain position to achieve the desired amount of offset. The system can be used with Biomet's Comprehensive® Shoulder System or Biomet's BioModular® Shoulder System depending upon which taper is used (i.e., in order to use with the Comprehensive® shoulder stem, the Comprehensive® Taper Adaptor must be used).

Intended Use: The Versa-Dial™ Humeral Head Prosthesis is intended for:

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.

Humeral components with a MacroBond® surface coating are indicated for either cemented or uncemented press-fit applications.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE 574.267.6639 ■ FAX 574.267.8137 ■ E-MAIL biomet@biomet.com

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510(k) Summary: Versa-Dial™ Humeral Head Prosthesis
Biomet Manufacturing Corp.

Humeral/glenoid components with a porous coated surface coating are indicated for either cemented or uncemented biological fixation applications. (Metal backed glenoid components offer optional screw fixation.)

Polyethylene glenoid components not attached to a metal back are indicated for cemented application only.

The Versa-Dial™ Humeral Head Prosthesis is intended for use only with the Comprehensive® Shoulder Stems (Fracture, Primary and Revision), the Bio-Modular® Shoulder Stems, and the glenoid components of the Bio-Modular® Shoulder System.

The device is a single use implant.

Summary of Technologies: The technological characteristics (material, design, sizing, indications) of the Versa-Dial™ Humeral Head Prosthesis are similar or identical to the predicate devices. The device has been redesigned since it was cleared in K040610. The redesigned Versa-Dial™ taper adaptor is comprised of Ti-6Al-4V; the predicate Versa-Dial™ taper adaptor is made of Co-Cr-Mo. The indicia on the underside of the new device have changed from numbers to letters.

Non-Clinical Testing: Non-clinical laboratory testing was 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

JUN 12 2006

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

Re: K060716
Trade/Device Name: Versa-Dial™ Humeral Head Prosthesis
Regulation Number: 21 CFR 888.3670
Regulation Name: Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBF, KWT, KWS, HSD
Dated: March 16, 2006
Received: March 17, 2006

Dear Ms. Alexander:

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 (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

K060716

Indications for Use

510(k) Number (if known):_____

Device Name: Versa-Dial™ Humeral Head Prosthesis

Indications For Use:

The Versa-Dial™ Humeral Head Prosthesis is intended for:

1) Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis.
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6) Difficult clinical management problems, including cuff tear arthropathy, where other methods of treatment may not be suitable or may be inadequate.

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The device is a single-use implant.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___NO___ (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)

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

510(k) Number K060716