K043100

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FEB 17 2005

BIOMET

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.
56 East Bell Drive
Warsaw, IN 46582
FDA Registration #: 1825034

Contact Person: Gary Baker
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587
Phone: (574) 267 - 6639
FAX: (574) 372 - 1683

Proprietary Name: Bio-Modular® Shoulder System – Hydroxyapatite Coated Glenoid Components

Common Name: Shoulder prosthesis

Classification Name: The Bio-Modular® Shoulder System – Hydroxyapatite Coated Glenoid Components are included in the following classification:

1. Shoulder Joint, Metal/Polymer/Metal, Non-Constrained or Semi-constrained, Porous Coated, Uncemented Prosthesis 21 CFR § 888.3670

The Bio-Modular® Shoulder System has been cleared for:

1. Shoulder Joint, Metal/Polymer/Metal, Non-Constrained or Semi-constrained, Porous Coated, Uncemented Prosthesis 21 CFR § 888.3670
2. Shoulder Joint, Metal/Polymer, Non-constrained, Cemented Prosthesis 21 CFR §888.3650
3. Prosthesis, Shoulder, Semi-constrained, Metal/Polymer, Cemented 21 CFR § 888.3660
4. Shoulder Joint, Humeral, "Hemi-Shoulder," Metallic, Uncemented Prosthesis 21 CFR § 888.3690

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Bio-Modular® Shoulder System (K030710) – Biomet Inc.

Device Description: The Bio-Modular® Shoulder System is a set of components intended for total or hemi shoulder arthroplasty. It consists of humeral stems, humeral heads, and glenoid components. The only change to this system proposed by this submission is the addition of Hydroxyapatite (HA) coating to the glenoid components that utilize metal backs and are intended for biological fixation with optional screw fixation. The HA coated glenoid components are intended only for total shoulder arthroplasty.

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

SHIPPING ADDRESS
56 E. Bell Drive
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OFFICE
574.267.6639 ■ FAX
574.267.8137 ■ E-MAIL
biomet@biomet.com

Intended Use:

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 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.
- 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).
- Glenoid components with Hydroxyapatite (HA) coating applied over the porous coating are indicated only for uncemented biological fixation applications. (Metal backed glenoid components offer optional screw fixation).
- Humeral components with a non-coated (Interlok®) surface are indicated for cemented application only.
- Polyethylene glenoid components not attached to a metal back are indicated for cemented application only.

The Comprehensive Humeral Fracture Stem is intended for use with the Bio-Modular® humeral heads and glenoid components.

The Versa-Dial™ Humeral Head Prosthesis is intended for use only with the Comprehensive Humeral Fracture Stem and the glenoid components of the Bio-Modular® Shoulder System.

Summary of Technologies:

The Bio-Modular Shoulder System with the Hydroxyapatite coated glenoid components has the same intended use, the same mechanical design, the same functional characteristics, and is made of the same titanium alloy as the predicate device.

Non-Clinical Testing: The modified devices were found to be substantially equivalent to the predicate devices.

Clinical Testing: No clinical testing was 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

FEB 17 2005

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

Re: K043100
Trade Name: Bio-Modular® Shoulder System–Hydroxyapatite Coated Glenoid Components
Regulation Number: 21 CFR 888.3670
Regulation Name: Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: MBF
Dated: January 14, 2005
Received: January 18, 2005

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.

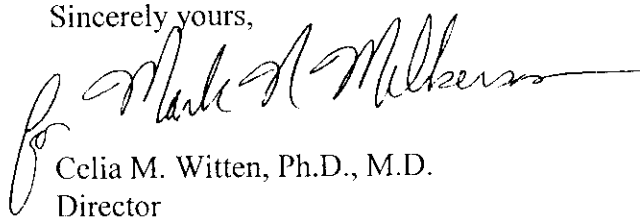
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

K043100

Indications For Use

510(k) Number (IF KNOWN)_____

Device Name: Bio-Modular® Shoulder System – Hydroxyapatite Coated Glenoid Components

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Prescription Use _____X_____ and/or Over–The–Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 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)

Mark N Milhouse

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

510(k) Number K043100