MAY 30 2006

BIOMET

K060692 p.1/2

510(k) Summary

Preparation Date: March 13, 2006

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Susan Alexander

Proprietary Name: Comprehensive® Primary Shoulder Stems

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:
- Bio-Modular® Shoulder System; Biomet Manufacturing Corp. (K030710)
- Comprehensive® Humeral Fracture Stems; Biomet Manufacturing Corp. (K023063)
- Integrated™ Shoulder System (Kirschner Shoulders with Titanium Plasma Spray); Biomet, Inc. (K961260)

Device Description:
The Comprehensive® Primary Shoulder Stems are humeral stems comprised of titanium alloy. The stems are available in various lengths and sizes. Portions of the devices are coated with plasma-spray titanium porous coating. The taper geometry of the new devices is the exactly the same as the predicate Comprehensive® Humeral Fracture Stems (K023063). The new devices are comprised of the exact same material as the predicate Bio-Modular® Shoulder System stems (K030710). The Comprehensive® Primary Shoulder Stems are designed to be used with Biomet's Bio-Modular® and Versa-Dial™ humeral heads and can be used in hemi or total shoulder arthroplasty.

Intended Use: The Comprehensive® Primary Shoulder Stems are indicated 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/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.)

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

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
574.267.6639

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574.267.8137

E-MAIL
biomet@biomet.com

The Comprehensive® Primary Shoulder Stems are intended for use only with the Bio-Modular® humeral heads and glenoid components and the Versa-Dial™ humeral head components.

The devices are single-use implants.

Summary of Technologies: The technological characteristics (material, design, sizing, indications) of the Comprehensive® Primary Shoulder Stems are similar or identical to the predicate devices.

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.

510(K) ROUTE SLIP
TRADITIONAL

3/17 TSG

510(k) NUMBER K060692 PANEL OR DIVISION DGRND BRANCH

ELECTRONIC SUBMISSION N

TRADE NAME COMPREHENSIVE PRIMARY SHOULDER STEMS

COMMON NAME SHOULDER PROSTHESIS

PRODUCT CODE ___

APPLICANT BIOMET MANUFACTURING CORP.
SHORT NAME BIOMETE
CONTACT SUSAN ALEXANDER
DIVISION
ADDRESS PO BOX 587
56. E. BELL DRIVE
WARSAW, IN 465810587
PHONE NO. (574) 267-6639 FAX NO. (574) 372-1683

MANUFACTURER BIOMET MANUFACTURING CORP. REG NO. 1450662
STERIS ISOMEDIX SERVICES 1450662

DATE ON SUBMISSION 13-MAR-2006 DATE DUE POS 29-APR-2006

DATE RECEIVED IN ODE 15-MAR-2006 75th DAY 29-MAY-2006

DECISION ___ DECISION DATE ___

Is this 510(k) identified as a Class III device ___YES ✓NO RB
Is this 510(k) the result of additional information ___YES ✓NO

CD Enclosed

Reassn SE
gss 5/24/06

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 30 2006

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

Re: K060692
Trade/Device Name: Comprehensive Primary Shoulder Stems
Regulation Number: 21 CFR 888.3670
Regulation Name: Shoulder joint metal/polymer/metal non-constrained or semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBF, KWT, KWS, HSD
Dated: March 13, 2006
Received: March 15, 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.

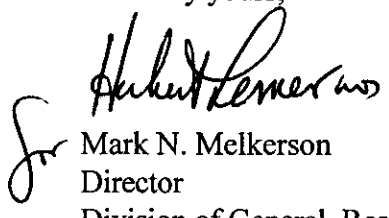
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K060692

Indications for Use

510(k) Number (if known):_____

Device Name: Comprehensive® Primary Shoulder Stems

Indications For Use:

The Comprehensive® Primary Shoulder Stems are intended for hemi or total shoulder replacement:

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/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.)

The Comprehensive® Primary Shoulder Stems are intended for use only with the Bio-Modular® humeral heads and glenoid components and the Versa-Dial™ humeral head components.

The devices are single-use implants.

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 K060692