MAY 2 4 2012

BIOMET®
MANUFACTURING CORP.

510(k) Summary

Preparation Date: 20 September, 2011

Applicant/Sponsor:
Biomet Manufacturing Corp.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587
FDA Registration Number: 1825034

Contact Person:
Gary Baker, MS RAC
Senior Regulatory Specialist
Biomet Orthopedics LLC.
P.O. Box 587
Warsaw, Indiana 46581-0587
Phone: (574) 267-6639 Ext. 1568
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gary.baker@biomet.com

Proprietary Name: Compress® Segmental Humeral Replacement System

Common Name: Proximal or Distal Humeral Replacement prostheses

Classification Name: MBF - Shoulder joint metal/polymer/metal non-constrained or semi-constrained porous-coated uncemented prosthesis.

KWS – Shoulder joint metal/polymer semi-constrained cemented prosthesis

KWT - Shoulder joint metal/polymer non-constrained cemented prosthesis

JDC – Elbow joint metal/polymer constrained cemented prosthesis

Mailing Address:
P.O. Box 587
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www.biomet.com

Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Biomet – K101475 -	Compress® Segmental Femoral Replacement System (Anti-Rotation Spindles)
Biomet – K062998 -	Compress® Segmental Femoral Replacement System (Short Spindle and Anchor Plug)
Biomet – K033280 -	Discovery™ Elbow – Mosaic™ Distal Humeral Replacement System
Biomet – K020045 -	3-Piece Proximal Humeral Replacement System (Mosaic)

Device Description:

The Compress® Segmental Humeral Replacement System is a metallic segmental fixation system intended to replace the resected part of the humerus in cases of severe bone loss. The design of the Compress® System allows a compressive load to be applied at the prosthetic implant-bone interface at the time of device insertion. This is accomplished through a spring system built into the stem.

Intended Use:

The Compress® Segmental Humeral Replacement System is intended to replace the resected part of the humerus in cases of severe bone loss in either the proximal or distal humerus. The Compress® Segmental Humeral Replacement System components are intended for uncemented use.

Indications for Use:

The Compress® Segmental Humeral Replacement System is indicated for:

1. Correction or revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.
2. Tumor resections.
3. Revision of previously failed total joint arthroplasty.
4. Trauma.

The Compress® Segmental Humeral Replacement System components are intended for uncemented use.

The Discovery Elbow components when used in conjunction with the Compress® Segmental Humeral Replacement System are restricted to the Compress® Segmental Humeral Replacement System indications and are intended to be inserted with bone cement.

The Modular Hybrid Glenoid when used in conjunction with the Compress® Segmental Humeral Replacement System is restricted to the Compress® Segmental Humeral Replacement System indications and is intended to be used with bone cement. The optional porous titanium peg may be inserted without bone cement. The optional polyethylene peg should be inserted with bone cement.

Summary of Technologies:

The Compress® Segmental Humeral Replacement System is a set of Compliant – Pre-Stress implants that replace the humeral stems that would normally be used during a proximal or distal humeral replacement surgery.

Non-Clinical Testing:

MT-5325 – Mini Compress® Taper Fatigue Test:
Cyclic Fatigue testing of the Mini Compress® taper indicated that all test specimens passed cyclic fatigue testing to ten million cycles without failure.

MT-5326 – Mini Compress® Pull-off Test:
Taper pull-off testing was conducted to determine the pull-off strength of the Mini Compress® taper. Each individual specimen exceeded the minimum acceptance criterion, as did the average pull-off strength.

Clinical Testing:

Clinical testing was not performed to demonstrate substantial equivalence of the subject Compress® Segmental Humeral Replacement System components with the predicate Compress® Segmental Femoral Replacement System components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 2 4 2012

Biomet Manufacturing Corporation
% Mr. Gary Baker, MS RAC
Senior Regulatory Specialist
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581-0587

Re: K112905
Trade/Device Name: The Compress® Segmental Humeral Replacement System
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, KWS, KWT, JDC
Dated: May 08, 2012
Received: May 10, 2012

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

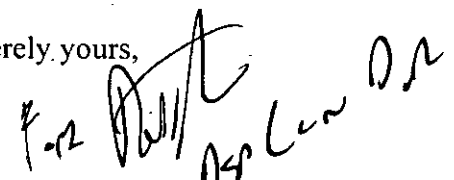
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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

Enclosure

K112905 p.1/1

Indications for Use

510(k) Number (if known):_____

Device Name: Compress® Segmental Humeral Replacement System

Indications For Use:

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Prescription Use ___Yes___ 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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112905