

K123297



NOV 20 2012

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

SUBMITTER INFORMATION	
Name	Biomet Manufacturing Corp.
Address	56 East Bell Drive Warsaw, IN 46582
Phone number	(574) 267-6639
Fax number	(574) 371-1027
Establishment Registration Number	1825034
Name of contact person	Patricia Sandborn Beres Senior Regulatory Specialist Biomet Manufacturing Corp.
Date prepared	October 16, 2012
NAME OF DEVICE	
Trade or proprietary name	Compress® Segmental Humeral Replacement System
Common or usual name	Humeral stem prosthesis
Classification name	Shoulder joint/metal/polymer/metal non-constrained or semi-constrained porous-coated uncemented prosthesis
Classification panel	Orthopedics
Regulation	21 CFR 888.3670
Product Code(s)	MBF
Legally marketed device(s) to which equivalence is claimed	Compress® Segmental Humeral Replacement System K112905
Reason for 510(k) submission	Add compatibility to the Comprehensive® Segmental Revision System (SRS), 510(k) 111746.
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 Compress® Segmental Humeral Replacement System components are intended for uncemented use. 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 of the device	Replacement of the resected part of the humerus

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<p>Indications for use</p>	<p>The Compress® Segmental Humeral Replacement System is indicated for:</p> <ol style="list-style-type: none"> 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. <p>The Compress® Segmental Humeral Replacement System components are intended for uncemented use.</p>
<p>PERFORMANCE DATA</p>	
<p>Summary Of Non-Clinical Tests Conducted For Determination Of Substantial Equivalence</p>	
<p>No non-clinical data was submitted</p>	
<p>Summary of clinical tests conducted for determination of substantial equivalence and/or of clinical information</p>	
<p>No clinical data submitted</p>	
<p>CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA</p>	
<p>No clinical or non-clinical data was necessary for a determination of substantial equivalence.</p>	

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Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

November 20, 2012

Biomet Manufacturing Corporation
% Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
P.O. Box 587
Warsaw, Indiana 465801

Re: K123297

Trade/Device Name: 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: II

Product Code: MBF

Dated: October 24, 2012

Received: October 25, 2012

Dear Ms. Beres:

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,

Erin I. Keith

Mark N. Melkerson
Director

Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123297

Device Name: Compress® Segmental Humeral Replacement System

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.

Prescription Use YES
(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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Anton E. Dmitriev, PhD
Division of Orthopedic Devices

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