

K101475



510(k) Summary

Preparation Date: 6/16/10
Applicant/Sponsor: Biomet Manufacturing Corp.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

JUN 18 2010

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: Compress® Segmental Anti-Rotation Spindles

Common Name: Segmental Femoral Stem Component

Classification Name: JDL, Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis (21 CFR §888.3320)
KWA, Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis (21 CFR §888.3330)
Hip Joint, Metal/Polymer, Semi-Constrained, Cemented Prosthesis (21 CFR §888.3350)
Knee Joint, Femorotibial, Metal/Polymer Constrained, Cemented Prosthesis (21 CFR §888.3510)

The compatible components included in this submission have the following classifications:

Subsequent Product Codes: JDI, Hip Joint, Metal/Polymer, Semi-Constrained, Cemented Prosthesis (21 CFR §888.3350)
KRO, Knee joint femorotibial metal/polymer constrained cemented prosthesis (21 CFR §888.3510)
KWY, Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (21 CFR §888.3390)
KWZ, Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR §888.3310)
LPH, Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR §888.3358)
LZO, Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR §888.3353)
LZY, Hip joint (hemi-hip) acetabular metal cemented prosthesis (21 CFR §888.3370)
MEH, Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR §888.3353)

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Warsaw, IN 46582

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Compress® Segmental Femoral Replacement System (Short Spindle and Anchor Plugs) – K062998

Compress® Segmental Femoral Replacement System – K043547

Device Description: The Compress® Segmental Anti-Rotation Spindles are not joint replacements but rather a method of fixing a segmental joint replacement to the patient's host bone. It utilizes the same spring-enhanced, stress-sharing design as the predicate Compress® Segmental Femoral Replacement System to generate stress on the host bone which helps prevent bone atrophy and promotes bone growth. It is intended to be used in conjunction with a knee or hip implant.

The complete device consists of an anchor plug, a spindle and either a proximal or distal femoral component. This 510(k) addresses modifications to the spindles. Holes are being added to the collar of the spindles to allow placement of pins to prevent rotation of the component during the initial weeks following implantation. Additional sizes of spindles are also being added to the line.

Intended Use: The Compress® Segmental Femoral Replacement System is indicated for:

1. Correction of 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 Femoral Replacement System components are intended for uncemented use.

Summary of Technologies: The Compress® Segmental Anti-Rotation Spindles incorporate the same technology as the predicate devices.

Non-Clinical Testing: Mechanical testing (resistance to rotational torque) and engineering analyses (greater wall thickness, smaller pin holes) of the Compress® Segmental Anti-Rotation Spindles demonstrated that the device will functional within its intended use compared to the predicate device.

Clinical Testing: None provided as a basis for substantial equivalence.



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

Biomet Manufacturing Corporation
% Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
56 East Bell Drive, P.O. Box 587
Warsaw, Indiana 46581-0587

JUN 18 2010

Re: K101475

Trade/Device Name: Compress[®] Segmental Anti-Rotation Spindles

Regulation Number: 21 CFR 888.3330

Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis

Regulatory Class: III

Product Codes: KWA, JDL, KRO, KWZ, JDI, LZO, MEH, LPH, KWY

Dated: May 26, 2010

Received: May 28, 2010

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.

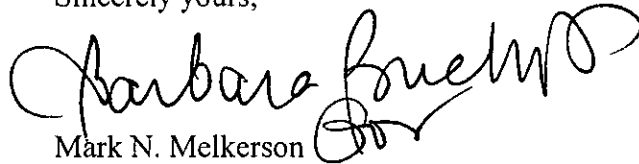
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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" (21 CFR 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

Indications for Use

510(k) Number (if known): K101475

Device Name: Compress® Segmental Anti-Rotation Spindles

Indications for Use:

The Compress® Segmental Femoral Replacement System is indicated for:

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

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

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)

[Handwritten Signature]

Division Sign-Off
Division of Surgical, Orthopedic,
and Restorative Devices

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