510(k) Summary

Preparation Date: 1/8/2007

JAN 19 2007

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

Contact Person: Jing Xie, Ph.D.
Biomet Manufacturing Corp.

Proprietary Name: Compress® Segmental Femoral Replacement System (Short Spindle and Anchor Plug)

Common Name: Segmental Femoral Stem Component

Classification Name: 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 Compress® Proximal Femoral Components, OSS® System components, compatible heads, liners, shells, screws, knee femoral and tibial 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)
JDL, Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis (21 CFR §888.3320)
KRO, Knee joint femorotibial metal/polymer constrained cemented prosthesis (21 CFR §888.3510)
KWA, Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis (21 CFR §888.3330)
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)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
Compress® Segmental Femoral Replacement System – K043547 (Biomet Manufacturing Corp.)

Device Description: The Compress® Segmental Femoral Replacement System (Short Spindle and Anchor Plug) utilizes a spring-enhanced and stress-sharing design; 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 device consists of the three main components, the Anchor Plug, Spindle, and the Taper Adapter.

Intended Use:

Indications for Use:

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 (Short Spindle and Anchor Plug) components are intended for uncemented use only.

Summary of Technologies: The Compress® Segmental Femoral Replacement System (Short Spindle and Anchor Plug) utilizes the same spring-enhanced, stress-sharing design as the predicate Compress® device to generate stress on the host bone which helps prevent bone atrophy and promotes bone growth. The technological characteristics of the Compress® Segmental Femoral Replacement System (Short Spindle and Anchor Plug) is identical to the predicate device. All the dimensional specifics of these components are similar to those of the predicate device. The Compress® Segmental Femoral Replacement System (Short Spindle and Anchor Plug) is used in conjunction with the same hip or knee components as the predicate device. Finally, the Compress® Segmental Femoral Replacement System (Short Spindle and Anchor Plug) is made from the same materials conforming to the same standards as the predicate device.

Non-Clinical Testing: Successful mechanical testing on Compress® Segmental Femoral Replacement System (Short Spindle and Anchor Plug) indicated that the device is functional within its intended use and substantially equivalent to the predicate device in performance characteristics.

Clinical Testing: None 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

APR 23 2009

Biomet Manufacturing Corp.
% Jing Xie, Ph.D.
Manager, Clinical Affairs
P. O. Box 587
Warsaw, Indiana 46581-0587

Re: K062998
Trade/Device Name: Compress Segmental Femoral Replacement System (Short Spindle and Anchor Plug)
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: III
Product Code: KWA, JDL, KRO, KWZ, JDI, LZO, MEH, LPH, KWY
Dated: January 12, 2007
Received: January 12, 2007

Dear Dr. Xie:

This letter corrects our substantially equivalent letter of January 19, 2007.

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 (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 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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 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

Indications for Use

510(k) Number (if known): K062998

Device Name:

Compress® Segmental Femoral Replacement System (Short Spindle and Anchor Plug)

Indications for Use:

Indications:

1. Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.
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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)

Barbara Bueno

(Division S...)
Division of ...eral, Restorative,
and Neuro... Devices

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