BIOMET ORTHOPEDICS, INC.

510(k) Summary

JUN 11 2008

Preparation Date: March 31, 2008

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: Segmental Distal Femoral Components and Proximal Femoral Bodies with a Compress® Female Taper

Common Name: Proximal or distal femoral replacement components

Classification Names:
- Hip Joint, Metal/Polymer, Semi-Constrained, Cemented Prosthesis (21 CFR §888.3350)
- Knee Joint, Femorotibial, Metal/Polymer Constrained, Cemented Prosthesis (21 CFR §888.3510)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
- Compress® Segmental Femoral Replacement System K043547 & K062998
- Orthopedic Salvage System (OSS™) K002757& K052685

Device Description:
The Segmental Distal Femoral Components with a Compress® Female Taper are designed to replace the distal end of the femur including the knee articulating surface. The Proximal Femoral Bodies with a Compress® Female Taper are designed to replace the proximal end of the femur including the hip articulating surface. These components are intended for use with Biomet's Compress® Segmental Femoral and Orthopedic Salvage Systems. The new devices that are the subject of this 510(k) have a taper bore that is directly compatible with the taper of the Compress® spindle eliminating the need for a taper adapter and allowing for smaller resection lengths.

Intended Use:
Biomet's Segmental Distal Femoral Components are intended for use in total knee replacement and the Proximal Femoral Bodies are intended for use in hip replacement procedures. Specific indications for these devices are:

1. Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis or traumatic arthritis.
2. Correction of varus, valgus or post traumatic deformity
3. Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.
4. Ligament deficiencies

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5. Tumor resections
6. Treatment of non-unions, femoral neck and trochanteric fracture of the proximal femur with head involvement, unmanageable using other techniques
7. Revision of previously failed total joint arthroplasty
8. Trauma

These devices are to be used with bone cement unless a proximal femur is indicated for use (USA)

When used with Biomet's Compress® Segmental Femoral Replacement System, the indications for use are uncemented application in cases of:

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.

Summary of Technologies: The Segmental Distal Femoral Components and Proximal Femoral Bodies with Compress® Female Taper have similar technologies as the predicate devices.

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

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

JUN 11 2008

Biomet, Inc.
% Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K080330
Trade/Device Name: Segmental Distal Femoral Components and Proximal Femoral Bodies with Compress® Female Taper
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulation Class: Class II
Product Code: KRO, JDI
Dated: June 3, 2008
Received: June 6, 2008

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.

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 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240)- 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240)- 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or 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): K080330

Device Name: Segmental Distal Femoral Components and Proximal Femoral Bodies with Compress® Female Tapers

Biomet's Segmental Distal Femoral Components are intended for use in total knee replacement and the Proximal Femoral Bodies are intended for use in hip replacement procedures. Specific indications for these devices are:

1. Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis or traumatic arthritis.
2. Correction of varus, valgus or post traumatic deformity
3. Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.
4. Ligament deficiencies
5. Tumor resections
6. Treatment of non-unions, femoral neck and trochanteric fracture of the proximal femur with head involvement, unmanageable using other techniques
7. Revision of previously failed total joint arthroplasty
8. Trauma

These devices are to be used with bone cement unless a proximal femur is indicated for use (USA)

When used with Biomet's Compress® Segmental Femoral Replacement System, the indications for use are uncemented application in cases of:

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.

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)

Neil R. Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080330