BIOMET®
MANUFACTURING CORP.

FEB 13 2009

510(k) Summary

Preparation Date: 22 December, 2008

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person:
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Proprietary Name: OSS 9cm Cobalt Chrome Tibial Bodies

Common Name: Knee System Tibial bodies.

Classification Code(s)/Name(s): KRO
Knee joint femorotibial metal/polymer constrained cemented prosthesis. 21 CFR §888.3510.

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: Oncology Salvage System* – K002757
*System name was changed to Orthopedic Salvage System

Device Description: 9cm resection tibial bodies

Intended Use:

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

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5. Tumor resection.
6. Treatment of non-unions, femoral neck fracture, and trochanteric fractures 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 (USA).

*Not applicable to Regenerex™ Ultra Porous Construct titanium knee augment usage, or any other knee component.

Summary of Technologies: The OSS 9cm Tibial Bodies are being modified to be made from Co-Cr-Mo Cobalt Chrome alloy rather than Ti-6Al-4V titanium alloy.

Non-Clinical Testing: Non-clinical testing was not considered necessary to establish substantial equivalence to the predicate device(s).

Clinical Testing: Clinical testing was not considered necessary to establish substantial equivalence to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Biomet Manufacturing Corp.
% Gary Baker, MS, RAC
Regulatory Specialist
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K083827
Trade/Device Name: OSS 9cm Cobalt Chrome Tibial Bodies
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulation Class: Class II
Product Code: KRO
Dated: January 20, 2009
Received: January 22, 2009

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.

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 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): K083827

Device Name: OSS 9cm Cobalt Chrome Tibial Bodies

Indications For Use:

1. Painful and disabled knee joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis, or traumatic arthritis.
2. Correction of varus, valgus or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement.
4. Ligament deficiencies.
5. Tumor resections.
6. Treatment of non-unions, femoral neck fracture, and trochanteric fractures 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 (USA).

*Not applicable to Regenerex™ Ultra Porous Construct titanium knee augment usage, or any other knee component.

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)

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

510(k) Number K083827