K052685 p1/2

BIOMET

OCT 27 2005

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Allison Koskey, Regulatory Affairs Specialist

Proprietary Name: Orthopedic Salvage System*- OSS

Common Name: *OSS Bodies*

Classification Name: -Prosthesis, Hip, semi-constrained, metal/polymer, cemented (888.3350, 87 JDI)
-Prosthesis, Knee, femorotibial, constrained, cemented, metal/polymer (888.3510, 87 KRO)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
Orthopedic Salvage System- OSS (K002757)

Device Description: The Orthopedic Salvage System- *OSS* offers a variety of component options for the treatment of patients that require proximal femoral, distal femoral, total femur, or proximal tibial replacements, as well as, resurfacing components for the proximal tibial and distal femur.

Indications for Use:

1) Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved
2) Correction of varus, valgus, functional 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 fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques
7) Trauma
8) Revision of previously failed total joint arthroplasty

These devices are single use implants.

These devices are for cemented use only.

Summary of Technologies: The designs, intended use, contraindications, and design specifications of the subject components are similar or identical to their predicate counterparts. This submission allows for additional sizing options for the OSS bodies.

* Formerly known as the Oncology Salvage System- OSS

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P.O. Box 587
Warsaw, IN 46581-0587

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574.267.6639

FAX
574.372.1683

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Non-Clinical Testing: An engineering analysis was performed on the modified and predicate devices comparing their profiles. The results indicated that the device was functional within its intended use.

Clinical Testing: Clinical testing was not required for the predicate device. Therefore, this submission contains no clinical testing.

* Formerly known as the Oncology Salvage System- OSS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2005

Allison Koskey
Regulatory Specialist
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K052685
Trade/Device Name: Orthopedic Salvage System - OSS
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: II
Product Codes: KRO, JDI
Dated: September 26, 2005
Received: September 28, 2005

Dear Ms. Koskey:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting 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): K052685

Device Name: Orthopedic Salvage System – OSS

Indications For Use: The OSS bodies are indicated for cemented use only in cases of:

1) Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved
2) Correction of varus, valgus, functional 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 fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques
7) Trauma
8) Revision of previously failed total joint arthroplasty

Prescription use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use___ 1 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 K052685

Page 1 of 1