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AUG 10 2005

BIOMET

510(k) Summary

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

Contact Person:
Gary Baker
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587
Phone: (574) 267-6639
FAX: (574) 372-1683

Proprietary Name:
RS (Reduced Size) OSS (Orthopedic Salvage System)
Additional Components

Common Name:
Orthopedic Salvage Hip, Knee, Tibia, or Total Femur

Classification Name:
Prosthesis, Knee Femorotibial, Constrained, Cemented, Metal/Polymer.

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Oncology Salvage System – K002757 (Biomet Inc.)
Reduced Size Oncology System – K021260 (Biomet Inc.)

Device Description: The RS OSS Additional Components are a series of components including distal femoral resurfacing components in 3cm and 5cm resection lengths and distal femoral segmental components with either modular or elliptical bone interface surfaces in 7cm and 8.5cm resection lengths. The tibial tray components are non-modular in design with either short stems or long stems. The Proximal Tibial Sleeves have a modular design that utilizes either the short or long stem tibial trays to provide 3cm, 5cm, 7cm or 9cm of resection height. The resection tibial tray provides a non-modular 9cm resection height. The tibial augments are either 10mm or 20mm augment sizes. The 20mm augments are side specific. The 15° tibial bearings have been included and the extension bumper design has been modified. These components are intended to expand the available options for the Reduced Size Orthopedic Salvage System.

Intended Use:

Indications for Use:

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 or revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.
4. Ligament deficiencies.
5. Tumor resections.

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biomet@biomet.com

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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.

The RS OSS Additional Components are intended for cemented use only.

Summary of Technologies: The RS OSS Additional Components are made from the same materials conforming to the same standards and utilize the same manufacturing, packaging and sterilization processes as the predicate devices.

Non-Clinical Testing: Mechanical testing and engineering justification demonstrate that the RS OSS Additional Components are substantially equivalent to the predicate components.

Clinical Testing: Clinical testing was not necessary to determine substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 10 2005

Mr. Gary Baker
Regulatory Specialist
Biomet Manufacturing Corp.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K051479
Trade/Device Name: RS (Reduced Size) OSS (Orthopedic Salvage System) Components
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: II
Product Code: KRO
Dated: July 21, 2005
Received: July 22, 2005

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.

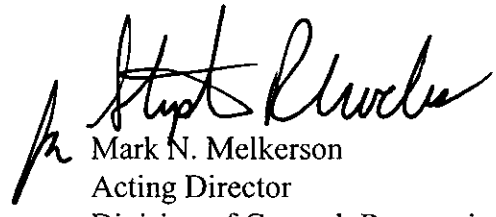
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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

Statement of Indications For Use

510(k) Number (IF KNOWN): K051479

Device Name: RS(Reduced Size) OSS (Orthopedic Salvage System) Components

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 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. Trauma.
8. Revision of previously failed total joint arthroplasty.

The RS OSS Components are intended for cemented use only.

Prescription Use __X__ (Per 21 CFR 801 Subpart D) OR Over-the-Counter Use_____ (Per 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 K051479