BIOMET®
MANUFACTURING CORP.

510(k) Summary

Preparation Date: 17 October, 2013

Applicant/Sponsor:
Biomet Manufacturing Corp.
56 East Bell Drive
Warsaw, IN 46582
FDA Registration #: 1825034

OCT 2 4 2013

Contact Person:
Gary Baker
Sr. Regulatory Specialist
56 East Bell Drive
Warsaw, IN 46582
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574-371-1027
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Proprietary Name: MAK OSS Femoral Knee Components

Common Name: Rotating Hinged Knee

Classification Code(s)/Name(s): KRO

888.3510 (KRO) – Knee joint femorotibial metal/polymer constrained cemented prosthesis

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

K083779 – MAK OSS Femoral Knee Components (Biomet)
K123501 – Orthopedic Salvage System (Biomet)

Device Description:
The MAK OSS Femoral Knee Components are intended to be used as an optional femoral knee component for use in conjunction with the cleared Orthopedic Salvage System. The MAK OSS Femoral Knee Components include either resurfacing or segmental femoral components that utilize the yoke and axle of the OSS System but limit extension of the knee to limit or prevent hyperextension.

Intended Use:
The MAK OSS Femoral Knee Components are intended for cemented use only.

Mailing Address:
P.O. Box 587
Warsaw, IN 46581-0587
Toll Free: 800.348.9500
Office: 574.267.6639
Main Fax: 574.267.8137
www.biomet.com

Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

Indications For Use:
Biomet's MAK OSS Femoral Knee Components are intended for use in conjunction with the OSS System for total knee replacement procedures. Specific indications for the OSS System 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 or revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.
4. Ligament deficiencies.
5. Tumor resections.
6. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by 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).

*Not applicable to Regenerex Ultra Porous Construct titanium knee augment usage (not licensed in Canada), or any other knee component.

When components of the Orthopedic Salvage System are used with Biomet's Compress Segmental Femoral Replacement System, they are intended for uncemented application and indicated for:

1. Correction or revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.
2. Tumor resections.
3. Revision of previously failed total joint arthroplasty.
4. Trauma.

Proposed Change(s):
This Traditional 510(k) is being submitted for design modifications made to the cleared Biomet MAK OSS Femoral Knee Components locking pin.

Technological Characteristics:

The modified MAK OSS locking pin is manufactured from the same wrought Co-Cr-Mo alloy conforming to ASTM F-1537 as the predicate MAK OSS locking pin. The pin diameter has been reduced by 0.002 inches and is longer than the predicate pin. It incorporates tabs to lock the pin in place. No other changes to the MAK OSS components are proposed by this submission. The intended use and the indications for use are identical to the predicate Systems.

Non-Clinical Testing:
Verification testing was conducted to demonstrate that the design modification made to the locking pin would not adversely affect the insertion or extraction of the locking pin. The testing demonstrated that the locking pins could be easily inserted and still maintained adequate extraction force.

Clinical Testing:
Clinical testing was not required to demonstrate substantial equivalence of the design modifications proposed to the cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 24, 2013

Biomet Orthopedics Corporation
Mr. Gary Baker
Senior Regulatory Specialist
56 East Bell Drive
Warsaw, Indiana 46582

Re: K131393
Trade/Device Name: MAK OSS Femoral Knee Components
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KRO
Dated: July 30, 2013
Received: August 2, 2013

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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 Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131393

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2. Tumor resections.
3. Revision of previously failed total joint arthroplasty.
4. Trauma.

Prescription Use YES 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)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices