BIOMET®

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

Submitter Information	
Name	Biomet Manufacturing LLC
Address	56 East Bell Drive Warsaw, IN 46581-0857
Phone number	(574) 372-1761
Fax number	(574) 372-1683
Establishment Registration Number	1825034
Name of contact person	Tracy Bickel Johnson, RAC
Date prepared	February 2014
Name of device	
Trade or proprietary name	Biomet Side Access Distal Femoral Expandable
Common or usual name	Constrained knee implant
Classification name / Regulation	Prosthesis, knee, femorotibial, constrained, cemented, metal/polymer (888.3510)
Classification panel	Orthopedic
Product Code(s)	KRO
Name of accessories	
Trade or proprietary name	Biomet Side Access Expandable Revolution Counter Biomet Side Access Expandable 5mm Straight Hex and Modular Ball Hex
Common or usual name	Instrument Specific Instrument- Surgical, Orthopedic Accessory Screwdriver
Classification name / Regulation	Implant specific Instrument- Prosthesis, knee, femorotibial, constrained, cemented, metal/polymer (888.3510) Screwdriver (888.4540)
Classification panel	Orthopedic
Product Code(s)	KRO HXX
Legally marketed device(s) to which equivalence is claimed	Biomet Expandable Knee (Biomet Manufacturing), K020381

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56 East Bell Drive
Warsaw, IN 46582

Reason for 510(k) submission	New device
Device description	The Biomet Side Access Distal Femoral Expandable Knee is an additional component to Biomet's Orthopedic Salvage System (OSS) that gives the surgeon the ability to expand the prosthesis as the patient grows. All expansion takes place where natural bone has been removed. The device does not lengthen existing bones. The expandable device is available in standard and Reduced Size (RS) and is compatible with Biomet OSS system components and Compress (CPS) devices.
Intended use of the device	Knee replacement
Indications for use	The Biomet Side Access Distal Femoral Expandable offers a treatment option for patients requiring distal femoral replacement who have not yet achieved full skeletal maturity (open epiphysis) or patients who require surgery who have significant residual leg length discrepancy. Indication for use of this device is most commonly tumor resection but could also involve osteoarthritis; rheumatoid arthritis; correction of deformity; and correction or revision of unsuccessful osteotomy, arthrodesis or previous joint replacement. The devices are single use implants intended for implantation with bone cement or with Biomet Compress®.
Summary of the Technologies	
The expandable device is available in standard and Reduced Size (RS) and is compatible with all Biomet OSS system components and Compress (CPS) devices. The Biomet Side Access Distal Femoral Expandable knee functions by means of an inner telescoping tube, also called the intercalary segment, which is moved by an adjusting screw that is coaxial with the tube. The expansion is performed in a manner simpler for the patient and the surgeon.	
PERFORMANCE DATA	
SUMMARY OF NON-CLINICAL TESTS	
Performance Test Summary-New Device	
Cyclic fatigue was conducted. Testing verified that the accuracy and performance of the system is adequate to perform as intended and to demonstrate substantial equivalence to the predicate device.	
SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION	
Clinical Performance Data/Information: N/A	
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA	
No clinical testing was necessary for a determination of substantial equivalence. The results of mechanical testing indicated the devices performed within the intended use, did not raise any new safety and efficacy issues and were found to be substantially equivalent to the 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

May 28, 2014

Biomet Manufacturing LLC
Ms. Tracy Bickel Johnson
Regulatory Global Project Manager
56 East Bell Drive
Warsaw, Indiana 46581-0857

Re: K140509
Trade/Device Name: Biomet Side Access Distal Femoral Expandable
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee Joint Femorotibial Metal/Polymer Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: KRO
Dated: February 25, 2014
Received: February 28, 2014

Dear Ms. Bickel Johnson:

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" (21 CFR 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,

Lori A. Wiggins

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

Enclosure

Indications for Use Statement

510(k) Number: K140509

Device Name: Biomet Side Access Distal Femoral Expandable

Indications For Use:

The Biomet Side Access Distal Femoral Expandable offers a treatment option for patients requiring distal femoral replacement who have not yet achieved full skeletal maturity (open epiphysis) or patients who require surgery who have significant residual leg length discrepancy. Indication for use of this device is most commonly tumor resection but could also involve osteoarthritis; rheumatoid arthritis; correction of deformity; and correction or revision of unsuccessful osteotomy, arthrodesis or previous joint replacement.

The devices are single use implants intended for implantation with bone cement or with Biomet Compress®.

Prescription Use X AND/OR Over-the-Counter _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 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