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 14, 2015

Biomet Incorporated
Mr. Bryan McMahon
Regulatory Affair Specialist
56 East Bell Drive
Warsaw, Indiana 46581

Re: K152621
Trade/Device Name: OSS/Acros IM Total Femur Rod
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JDI, KRO, JWH
Dated: September 10, 2015
Received: September 14, 2015

Dear Mr. McMahon:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K152621

Device Name
OSS/Arcos IM Total Femur Rod

Indications for Use *(Describe)*

OSS INDICATIONS

1. Painful and disabled 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 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 composed of OsseoTi (titanium alloy, not licensed in Canada) or a proximal femur is indicated for use (USA).

Biomet OSS Reduced size (RS) components offers a variety of component options for treatment in small adults and adolescents (12-21 years) that require proximal femoral, distal femoral, total femur, or proximal tibial replacement as well as, resurfacing components for the proximal tibia and distal femur (USA).

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

COMPRESS INDICATIONS

The Compress Segmental Femoral Replacement System is indicated for:
1. Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.
2. Tumor resections.
3. Revision of previously failed total joint arthroplasty.
4. Trauma.

The Compress Segmental Femoral Replacement System components are intended for uncemented use.
When components of the Orthopaedic Salvage System are used with Biomet's Compress Segmental Femoral Replacement System, the user should refer to the package insert contained with the Compress components for full prescription information.

EXPANDABLE INDICATIONS

The Biomet Side Access Distal Femoral Expandable offers a treatment option forpatients 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.

510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the OSS/Arcos IM Total Femur Rod 510(k) premarket notification.

Sponsor:
Biomet Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581
Establishment Registration Number: 1825034

Contact:
Bryan M. McMahon
Regulatory Affairs Specialist

Date:
October 12, 2015

Subject Device:
Trade Name: OSS/Arcos IM Total Femur Rod
Common Name: Oncology, Salvage Hip/Knee
Classification Name:

- JDI– Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented (21 CFR 888.3350)
- KRO– Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/Polymer (21 CFR 888.3510)
- JWH– Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer (21 CFR 888.3560)

Legally marketed devices to which substantial equivalence is claimed:

- K033871, K123501 – IM Total Femur – Biomet. Inc
- K912712, K090757 – Modular Hip – Biomet, Inc. (Taper Connection)
- K141331, K140509 - Biomet Orthopedic Salvage System – Biomet, Inc. (Indications)

Device Description

The OSS/Arcos IM Total Femur Rod is, in simplest terms, a metal rod that is inserted into the IM canal of a femur and connects a proximal femoral component to a distal femoral component. The aforementioned femoral components are secured to the rod by both a Morse taper and a screw; the proximal end features an “Arcos” taper while the distal end is an “OSS” taper. The Arcos taper is the same as that utilized by the devices in K090757 while the OSS taper is identical to that utilized by the predicate device.

The rods are slightly bowed to mimic the natural femur and find appropriate alignment. All rods have a diameter of 14 mm and are available in 1 cm length increments from 20 cm to 30 cm.

Figure 7.1: An example OSS/Arcos IM Total Femur Rod construct inside the IM canal of a femur.

The device is compatible with Biomet's Arcos proximal bodies and OSS distal femoral components.

Intended Use and Indications for Use

OSS INDICATIONS

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Summary of Technological Characteristics

The new devices are a modification to the predicate device (K033871, K123501) in the following ways:

- The proximal taper geometry is being modified
- The proximal screw packaged with the device is changing

All other technological characteristics remain unchanged.

Summary of Performance Data

Mechanical testing in support of the Arcos taper and proximal screw was previously supplied in K090757. These tests were performed on the worst-case Arcos constructs; as the OSS/Arcos IM Total Femur Rod does not present a new worst-case, this testing is sufficient show the subject device is as safe and effective as the predicate.

Substantial Equivalence Conclusion

The proposed and predicate IM Total Femur (K033871, K123501) devices have the same intended use and indications for use (K141331, K14050) and Taper Connection References (K912712, K090757). The proposed design changes do not alter the fundamental scientific technology shared by both the proposed and predicate IM Total Femur devices. The information provided in this submission demonstrates that the proposed device is as safe and effective as the predicate and does not raise different questions of safety and effectiveness than the predicate. Therefore, the proposed OSS IM Total Femur Rod is substantially equivalent to the cited predicate device(s).