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

June 25, 2015

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

Re: K142814
Trade/Device Name: Biomet Orthopaedic Salvage System (OSS™) - Proximal Femoral & Hybrid Tibial
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JDI, LPH, KRO
Dated: May 26, 2015
Received: May 28, 2015

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 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)*
K142814

Device Name
Biomet Orthopaedic Salvage System (OSS™)- Proximal Femoral & Hybrid Tibial

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 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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 PO Box 587 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	25 June 2015
Name of device	
Trade or proprietary name	Biomet Orthopaedic Salvage System (OSS)
Common or usual name	Knee/Hip Implants
Classification name / Regulation	Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented (21 CFR § 888.3350), Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented (21 § CFR 888.3358), Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/Polymer (21 CFR § 888.3510)
Classification panel	Orthopedic
Product Code(s)	JDI, LPH, KRO
Legally marketed device(s) to which equivalence is claimed	Biomet RS (Reduced Size) OSS Additional Components Primary predicate for proximal tibia (K021260), Biomet Vanguard Removable Molded Poly Tibia (K102580), Stryker/Howmedica GMRS All Poly Tibia (K031480/K992346), Biomet Segmental Distal Femoral Component and Proximal Femoral Bodies – Primary predicate for proximal femur (K080330), Biomet G7 OsseoTi Acetabular Shell (K140669), Biomet OSS Les Proximal Component (K021380), and Biomet Orthopaedic Salvage System-OSS (K141331) *Reference Items*: Biomet Reconstructive Wedges (K122770), Regenerex Knee Augments (K072336), and Orthopaedic Salvage System- OSS (K002757)

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56 East Bell Drive
Warsaw, IN 46582

Reason for 510(k) submission	New device
Device description	The new devices included in this submission are additional components to Biomet's Orthopaedic Salvage System (OSS) that offer surgeons additional prostheses options to be used in limb salvage reconstruction. The new devices include proximal femoral components and tibial components.
Intended use of the device	Proximal Femur, Total Femoral Reconstruction, and Proximal Tibia Reconstruction.
Indications for use	**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 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 new devices are modifications to the predicate devices (K021260, K102580, K031480/K992346, K080330, K140669, and K021380) in the following ways: • Hybrid Poly tibial components have metallic baseplate with polyethylene stem • Proximal femoral body is incorporated with an external male taper • Optional OsseoTi™ proximal femoral augment • Various spiked washer and bolt combinations The Hybrid Poly tibial components utilize a polyethylene stem that is mechanically locked to the metallic baseplate. A separate polyethylene bearing component (previously cleared) will be utilized as part of the constrained knee system. These components will primarily be used in adolescent patients that have an open epiphysis. The external taper post feature and external augment taper feature are incorporated so that new devices are compatible with other OSS components. An optional OsseoTi™ Proximal femoral augment can attach to the subject proximal femoral body for soft tissue attachment. The OsseoTi™ material and process for the devices included in this submission is identical to those components cleared in Biomet G7 OsseoTi Acetabular Shell (K140669) and Biomet Orthopaedic Salvage System-OSS (K141331).	
PERFORMANCE DATA	
SUMMARY OF NON-CLINICAL TESTS	
Performance Test Summary-New Device	
Device Fatigue Testing, proximal femoral and hybrid tibia	

Range-of-Motion (ROM) Analysis Material Characterization for OsseoTi™
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 device fatigue testing and material characterization studies 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.