DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 27, 2014

Biomet, Incorporated
Tracy Bickel Johnson
Regulatory Global Project Manager
56 East Bell Drive
Post Office Box 587
Warsaw, Indiana 46581

Re: K141331
Trade/Device Name: Biomet Orthopaedic Salvage System (OSS) Line Extension
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: September 24, 2014
Received: September 26, 2014

Dear Ms. Tracy 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" (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 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,

Lori A. Wiggins -S

for
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)*
K141331

Device Name
Biomet Orthopedic Salvage System (OSS) Line Extension

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.

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)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## 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<br>PO Box 587<br>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** | 22 August 2014 |
| **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, porous uncemented (21 CFR § 888.3350);<br>Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented (21 CFR § 888.3350);<br>Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/Polymer (21 CFR § 888.3510) |
| **Classification panel** | Orthopedic |
| **Product Code(s)** | LPH; JDI; KRO |
| **Legally marketed device(s) to which equivalence is claimed** | Biomet Orthopaedic Salvage System (K002757, K052685, K123501);<br>Biomet RS (Reduced Size) OSS Additional Components (K051479/K021260);<br>Zimmer Segmental System Trabecular Metal Proximal Tibial Component, Trabecular Metal Proximal Femoral Component, and Additional Segment with Male/Female Taper Components (K110940)<br>*Reference Item*: Biomet Reconstructive Wedges (K122770)<br>*Reference Item*: Regenerex Sleeve Augments (K072336) |
| **Reason for 510(k) submission** | New device |

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56 East Bell Drive
Warsaw, IN 46582

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|---|---|
| **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 distal femoral component, proximal femoral component, proximal tibial sleeve, diaphyseal segment, splined stem, diaphyseal augment and metaphyseal augment. |
| **Intended use of the device** | Proximal and Distal Femoral Reconstruction, Tibial Reconstruction. |
| **Indications for use** | OSS INDICATIONS<br>1. Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis, or traumatic arthritis.<br>2. Correction of varus, valgus, or posttraumatic deformity.<br>3. Correction or revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.<br>4. Ligament deficiencies.<br>5. Tumor resections.<br>6. Treatment of non-unions, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques. *<br>7. Revision of previously failed total joint arthroplasty.<br>8. Trauma.<br><br>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).<br><br>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).<br><br>* Not applicable to Regenerex Ultra Porous Construct titanium knee augment usage (not licensed in Canada), or any other knee component.<br><br>COMPRESS INDICATIONS<br>The Compress Segmental Femoral Replacement System is indicated for:<br>1. Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.<br>2. Tumor resections.<br>3. Revision of previously failed total joint arthroplasty.<br>4. Trauma. |

| | |
|---|---|
| | The Compress Segmental Femoral Replacement System components are intended for uncemented use.<br><br>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. |

**Summary of the Technologies**

The new devices are modifications to the predicate devices (K002757, K052685, K051479/K021260 and K110940) in the following ways:

- Distal femoral components (with optional augments) are modified with aesthetic profile update and an external taper post feature;
- Splined stems are modified with material change to CoCrMo;
- Diaphyseal segments are modified with an external augment taper feature and material change to CoCrMo;
- Proximal tibial sleeves are modified with material change to OsseoTi™ and additional suture holes for optional tissue attachment method utilizing optional spiked washers and bolts;
- Metaphyseal augments are modified with augment taper feature and material change to OsseoTi™;
- Diaphyseal augments are modified with material change to OsseoTi™ and geometry updates to be compatible with OSS devices

The external taper post feature and external augment taper feature are incorporated so that new devices are compatible with other OSS components (K002757, K052685, and K051479). Material change to CoCrMo for its material strength, and to OsseoTi™ to enhance the potential for bone integration. The OsseoTi™ material and process for the devices included in this submission is identical as which cleared in Biomet Reconstructive Wedges K122770. Cleaning of OsseoTi is identical to Regenerex materials which were previously cleared in K072336.

New proximal sleeves are updated with additional suture holes for optional use with spiked washers and bolts as optional secondary tissue fixation method. Primary tissue fixation method remains the same as predicate device.

**PERFORMANCE DATA**

**SUMMARY OF NON-CLINICAL TESTS**

**Performance Test Summary-New Device**

Device Fatigue Testing
Device Static Disassociation Testing
Tensile Properties Testing
Material Characterization for OsseoTi
Cleaning

| 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.<br>The results of device fatigue testing, static disassociation 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. |