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

September 15, 2014

Biomet, Inc.
Mr. Jason Dugger
Regulatory Affairs Specialist
56 East Bell Drive
Warsaw, Indiana 46581

Re: K142295
Trade/Device Name: Sirius Femoral Hip Stem
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JDI, LZO, KWZ, MEH, LPH, KWY, JDG, LZY, OQG, OQH, OQI, PBI, KWL
Dated: August 14, 2014
Received: August 18, 2014

Dear Mr. Dugger:

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ------- K142295

Device Name: **Sirius Femoral Hip Stem**

INDICATIONS FOR USE:

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision procedures where other treatment or devices have failed.

The Sirius Femoral Hip Stem is intended for cemented use only and may be used in partial and total hip arthroplasties.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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 Sirius Femoral Stem Size 30A Special 510(k) premarket notification.

Sponsor:

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

Contact:

Jason Dugger
Regulatory Affairs Specialist

Date: September 12, 2014

Subject Device:

Trade Name: Sirius Femoral Hip Stem
Common Name: Cemented Modular Hip Prosthesis
Classification Name:

- JDI– Prosthesis, Hip, Semi-Constrained, metal/Polymer, Cemented (21 CFR 888.3350)
- LZO- Hip joint metal/ ceramic/ polymer semi-constrained cemented or nonporous uncemented prostheses (21 CFR 888.3353)
- KWZ- Hip joint metal/ polymer constrained cemented or uncemented prosthesis (21 CFR 888.3310)
- MEH- Hip joint metal/ceramic/ polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353)
- LPH- Hip joint metal/ polymer/ metal semi-constrained porous-coated, uncemented prosthesis (21 CFR 888.3390)
- KWY- Hip joint femoral (hemi-hip) metal/ polymer cemented or uncemented prosthesis (21 CFR 888.3390)
- JDG- Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (21 CFR 888.3360)
- LZY- Hip joint (hemi-hip) acetabular metal cemented prosthesis (21 CFR 888.3370)
- OQG- Prosthesis, hip, semi-constrained, metal/polymer + additive, porous uncemented (21 CFR 888.3358)
- OQH- Hip, semi-constrained, cemented, metal/ polymer + additive, cemented (21 CFR 888.3350)
- OQI- Hip, semi-constrained, cemented, metal/ ceramic/ polymer + additive, porous uncemented (21 CFR 888.3353)
- PBI- Prosthesis, hip, constrained, cemented or uncemented, metal/ polymer, + additive (21 CFR 888.3310)

- KWL- Hip Joint Femoral (Hemi-Hip) Metallic Cemented or Uncemented Prosthesis (21 CFR 888.3360)

Legally marketed devices to which substantial equivalence is claimed:

- K130610 – Sirius Femoral Stem – Biomet, Inc.

Device Description

The Sirius Femoral Stem is a highly polished, double-tapered, cemented stem designed to reduce hip pain for patients and restore joint biomechanics and stability. The femoral stem is designed to fit patient femoral anatomies for primary or revision hip arthroplasties.

The proposed device is made from CoCrMo per ASTM F799.The features include a collarless, highly polished, double taper design with a rectangular proximal geometry. The distal portion of the stem has a progressive diminishing cross-section.

Intended Use and Indications for Use

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision procedures where other treatment or devices have failed.

The Sirius Femoral Hip Stem is intended for cemented use only and may be used in partial and total hip arthroplasties.

Summary of Technological Characteristics

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** The proposed and predicate Sirius Femoral Stem devices have the identical intended use.
- **Indications for Use:** The proposed and predicate Sirius Femoral Stem devices have identical indications for use.
- **Materials:** The proposed and predicate Sirius Femoral Stem devices are manufactured from CoCrMo per ASTM F799.
- **Design Features:** The proposed and predicate Sirius Femoral Stem devices incorporate the same design features.
- **Sterilization:** The proposed and predicate Sirius Femoral Stem devices are provided sterile via the same sterilization methods for single-use.

Summary of Performance Data

Results from mechanical tests demonstrate that the proposed Sirius Femoral Stem is substantially equivalent to the predicate femoral stems. A description of the tests performed on the proposed device is as follows:

- Proximal Fatigue Testing – ISO 7206-6
- Distal Fatigue Testing – ISO 7206-4
- Range of Motion – ISO 21535

Substantial Equivalence Conclusion

The proposed Sirius Femoral Stem has the same intended use and indications for use as the predicate devices. Performance test data demonstrates the device is as safe and effective and is substantially equivalent to the legally marketed predicate devices.