Biomet Manufacturing Corp.
Patricia Sandborn Beres
Regulatory Affairs Principal
56 East Bell Drive
Warsaw, Indiana 46580

February 8, 2018

Re: K173411
Trade/Device Name: Comprehensive Segmental Revision System (SRS)
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWT, KWS, MBF, JDC
Dated: January 11, 2018
Received: January 12, 2018

Dear Patricia Sandborn Beres:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -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)*

K173411

Device Name
Comprehensive Segmental Revision System (SRS)

Indications for Use *(Describe)*

Indications For Use:
The Comprehensive Segmental Revision System is intended for use in cases of:
1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Revision where other devices or treatments have failed.
4. Correction of functional deformity.
5. Oncology applications including bone loss due to tumor resection.

When used in a proximal or total humeral replacement, the Comprehensive Segmental Revision System is also intended for: Treatment of acute or chronic fractures with humeral head (shoulder) involvement, which are unmanageable using other treatment methods.

When used as a distal or total humeral replacement, the Comprehensive Segmental Revision System is also intended for: Treatment of acute or chronic fractures with humeral epicondyle (elbow) involvement, which are unmanageable using other treatment methods.

Biomet Comprehensive Segmental Revision System is indicated for use in a reverse application in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthropathy and/or previously failed shoulder joint replacement with a grossly deficient rotator cuff. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary. Reverse application is limited to proximal humeral replacement in the United States.

The Comprehensive Segmental Revision System is intended for use with or without bone cement in the proximal shoulder.

The Comprehensive Segmental Revision System is intended for use with bone cement in distal humeral and total humeral applications.

Tissue Attachment Augments provide the option for tissue stabilization and attachment.

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.

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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 Comprehensive Segmental Revision System (SRS) 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor:	Biomet Inc. 56 East Bell Drive PO Box 587 Warsaw, IN 46581 Establishment Registration Number: 1825034
Contact Person:	Patricia Sandborn Beres Regulatory Affairs Principal Telephone: (574-267-6639 ext. 1278) Fax: fax (574-371-1027)
Date:	February 2, 2018
Subject Device:	**Trade Name:** Comprehensive Segmental Revision System (SRS) **Common Name:** Shoulder/Elbow Replacement Prosthesis **Classification Name:** • PHX– shoulder prosthesis, reverse configuration (21 CFR 888.3660) • KWT - Shoulder joint metal/polymer non-constrained cemented prosthesis (21 CFR 888.3650) • KWS - Shoulder joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3660) • MBF Shoulder joint metal/polymer/metal non-constrained or semi-constrained porous coated uncemented prosthesis (21 CFR 888.3670) • JDC - Elbow joint metal/polymer constrained cemented prosthesis (21 CFR 888.3150)
Predicate Device:	Equinoxe Mega Prosthesis (Exactech) K143659
Secondary (Reference) Predicate:	Comprehensive Segmental Revision System (SRS) (Biomet) K111746, K112905 & K153398
Compatible Components Provided for reference:	Comprehensive Reverse Shoulder System (Biomet) K080642, K113069, K113121, K120121, K131353, K152754 TM Reverse Shoulder System (Zimmer) K052906,K060704, K121543, K122692, K130661, K133378

Purpose and Device Description:

The Comprehensive Segmental Revision System (SRS) is a multi-piece orthopedic implant designed to replace the shoulder joint. The device is designed specifically for use in cases where there is extensive bone loss requiring extramedullay replacement of bone. The components of the Comprehensive SRS system have previously been cleared for use in hemi and anatomic total shoulder replacement. The current submission is to expand the indications to include reverse shoulder applications. All components have been previously cleared.

Intended Use and Indications for Use:

The Comprehensive Segmental Revision System is intended for use in cases of:

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Revision where other devices or treatments have failed.
4. Correction of functional deformity.
5. Oncology applications including bone loss due to tumor resection.

When used in a proximal or total humeral replacement, the Comprehensive Segmental Revision System is also intended for:

Treatment of acute or chronic fractures with humeral head (shoulder) involvement, which are unmanageable using other treatment methods.

When used as a distal or total humeral replacement, the Comprehensive Segmental Revision System is also intended for:

Treatment of acute or chronic fractures with humeral epicondyle (elbow) involvement, which are unmanageable using other treatment methods.

Biomet Comprehensive Segmental Revision System is indicated for use in a reverse application in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthropathy and/or previously failed shoulder joint replacement with a grossly deficient rotator cuff. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is

necessary. Reverse application is limited to proximal humeral replacement in the United States.

The Comprehensive Segmental Revision System is intended for use with or without bone cement in the proximal shoulder.

The Comprehensive Segmental Revision System is intended for use with bone cement in distal humeral and total humeral applications.

Tissue Attachment Augments provide the option for tissue stabilization and attachment.

Summary of Technological Characteristics:

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

- **Intended Use:** Identical to predicates
- **Indications for Use:** Identical to predicates
- **Materials:** Similar or identical to predicates
- **Design Features:** Similar or identical to predicates
- **Sterilization:** Identical to predicates

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:** No new testing provided. The following testing from K111746 referenced:
  - Engineering analysis to determine weakest point of the construct
  - Engineering analysis to determine range of motion
  - Engineering analysis to justify smaller diameter long stems
  - Cantilever fatigue testing to compare stem strength to predicate
  - Cyclic loading followed by screw torque out to confirm augment stability
  - Engineering analysis for flange loading determination
  - Cyclic fatigue testing of humeral flange
  - Static Axial Separation of SRS taper junction
  - Static Axial Separation of Comprehensive taper junction
  - MR Compatibility to ASTM F2182-09
- **Clinical Tests:**
  - None provided

Substantial Equivalence Conclusion

The proposed expansion of indication for the Comprehensive SRS will give this system the same intended use and indications for use as the predicate Exactech device. The proposed device has similar technological characteristics to the predicate, and the information provided herein demonstrates that:

- any differences do not raise new questions of safety and effectiveness; and
- the proposed device is at least as safe and effective as the legally marketed predicate devices