July 12, 2023

Biomet Orthopedics
Alexandria Irwin
Regulatory Affairs Specialist
56 East Bell Drive
Warsaw, Indiana 46581

Re: K223631
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: June 15, 2023
Received: June 16, 2023

Dear Alexandria Irwin:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Farzana Sharmin -S
Digitally signed by Farzana Sharmin -S
Date: 2023.07.12 12:35:47 -04'00'

Farzana Sharmin, Ph.D.
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K223631

Device Name
Comprehensive Segmental Revision System(SRS)

Indications for Use *(Describe)*

The Comprehensive® Segmental Revision System is intended for use in cases of:
1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Revision where other devices or treatments have failed.
3. Correction of functional deformity.
4. 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. For the US and Canada only: reverse application is limited to proximal humeral replacement.

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. Tissue Attachment Augments are not available in all markets.

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.

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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 September 13, 2019.

Sponsor:

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

Contact Person:

Alexandria Irwin
Regulatory Affairs Specialist
Telephone: (1-574-373-0167)

Date:

July 11, 2023

Subject Device:

Trade Name: Comprehensive Segmental Revision System (SRS)
Common Name: Shoulder/Elbow Replacement Prosthesis

Classification Name:

- PHX– Shoulder joint metal/polymer semi-constrained cemented prosthesis (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 nonconstrained 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(s):

K173411	Comprehensive Segmental Revision System (SRS)	Biomet Manufacturing Corp

Reference Devices:

K111746	Comprehensive Segmental Revision System (SRS)	Biomet Inc
K172502	Comprehensive Augmented Glenoid Components, Comprehensive Standard Baseplate, Comprehensive Mini Baseplate	Biomet Manufacturing Corp

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K182516	Comprehensive Nano Stemless Shoulder	Biomet Manufacturing Corp

Purpose and Device

The Comprehensive Segmental Revision System (SRS) is a multi-piece orthopedic implant designed to replace the humerus up to and including the humeral side of the shoulder and elbow joints. The device is designed specifically for use in cases where there is extensive bone loss requiring extramedullary replacement of bone. The Tissue Attachment Augments provide the option for tissue stabilization and attachment.

The components of the Comprehensive SRS system(including the Modular Porous Plasma (PPS) Augments) have previously been cleared for use in hemi and anatomic total shoulder replacement in K111746. K173411 expanded the indications for the Comprehensive Segmental Revision System(SRS) to include revere shoulder applications, however at the time the PPS Augments were not being marketed, therefore they were not included in the submission.

The purpose of this submission is:

- To expand the indications to include reverse shoulder applications for the PPS Augments. The PPS Augments have been previously cleared in K111746.
- To document changes since original clearance for the PPS Augments
- To document changes since K173411 for the rest of the Comprehensive Segmental Revision (SRS)System

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. Revision where other devices or treatments have failed.
3. Correction of functional deformity.
4. 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. For the US and Canada only: Reverse application is limited to proximal humeral replacement.

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. Tissue Attachment Augments are not available in all markets.

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:** Similar 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/Justification:**
  - Coating Characterization
  - Fatigue Strength Report Flanges
  - Fatigue Strength Analysis Humeral Stems
  - Shot Peen Testing Summary
  - MRI
- **Clinical Tests:**
  - None provided

Substantial Equivalence Conclusion

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

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