Biomet Manufacturing Corp.
Aishwarya Pandey
Regulatory Affairs Specialist
56 East Bell Drive
Warsaw, Indiana 46582

March 15, 2023

Re: K214001
Trade/Device Name: Comprehensive® Shoulder System, Comprehensive® Reverse Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, PAO, KWT, MBF, HSD
Dated: December 14, 2021
Received: December 21, 2021

Dear Aishwarya Pandey:

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: 2023.03.15 21:34:53 -04'00'

For Jiping Chen, MD, Ph.D., M.P.H.
Division 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)*
K214001

Device Name
Comprehensive® Shoulder System, Comprehensive® Reverse Shoulder System
(Biomet® Comprehensive® Reverse Shoulder Screws)

Indications for Use *(Describe)*

Biomet Comprehensive Reverse Shoulder products are indicated for use 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.

The Comprehensive Reverse Shoulder is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.

Glenoid components with Hydroxyapatite (HA) coating applied over the porous coating are indicated only for uncemented biological fixation applications. The Glenoid Baseplate components are intended for cementless application with the addition of screw fixation.

Interlok® finish humeral stems are intended for cemented use and the MacroBond® coated humeral stems are intended for press-fit or cemented applications. Humeral components with porous coated surface coating are indicated for either cemented or uncemented biological fixation applications.

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*
K214001

Device Name
Comprehensive® Shoulder System, Comprehensive® Reverse Shoulder System
(Biomet® Comprehensive® Reverse Shoulder Products)

Indications for Use *(Describe)*

Biomet Comprehensive Reverse Shoulder products are indicated for use 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.

The Comprehensive Reverse Shoulder is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.

Titanium glenospheres are intended for patients with Cobalt Alloy material sensitivity. The wear of these devices has not been tested but, based on pin on disk testing, the wear rate is inferior to that of cobalt alloy glenospheres. A Cobalt Alloy glenosphere is the recommended component for reverse shoulder arthroplasty patients without material sensitivity to cobalt alloy.

Glenoid components with Hydroxyapatite (HA) coating applied over the porous coating are indicated only for uncemented biological fixation applications. The Glenoid Baseplate components are intended for cementless application with the addition of screw fixation.

Interlok® finish humeral stems are intended for cemented use and the MacroBond® coated humeral stems are intended for press-fit or cemented applications. Humeral components with porous coated surface coating are indicated for either cemented or uncemented biological fixation applications.

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Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K214001

Device Name
Comprehensive® Shoulder System, Comprehensive® Reverse Shoulder System
(Biomet® Shoulder Joint Replacement Prostheses)

Indications for Use *(Describe)*
1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Fractures of the proximal humerus, where other methods of treatment are deemed inadequate.
5. Difficult clinical management problems, including cuff arthropathy, where other methods of treatment may not be suitable or may be inadequate.
Optional use in revision: in some medical conditions (e.g. revision when healthy and good bone stock exists), the surgeon may opt to use primary implants in a revision procedure.

Humeral components with a porous coated surface coating are indicated for either cemented or uncemented biological fixation applications.

The Comprehensive® Modular Hybrid® Glenoid is intended to be implanted with bone cement. The optional porous titanium peg may be inserted without bone cement. The optional polyethylene peg should be inserted with bone cement.

The Comprehensive Humeral Positioning Sleeves are for cemented use only and are intended for use with the Comprehensive Fracture Stem.

The Versa-Dial Humeral Head Prosthesis is intended for use only with the Comprehensive Shoulder Stems (Fracture, Primary and Revision), and the glenoid components of the Comprehensive Shoulder System.

The Titanium Versa-Dial Humeral Head Prosthesis is indicated for patients with suspected cobalt alloy sensitivity. The wear properties of Titanium and Titanium alloys are inferior to that of cobalt alloy. A Titanium humeral head is not recommended for patients who lack suspected material sensitivity to cobalt alloy*

*The Titanium Versa-Dial Humeral Head Prosthesis is not for sale in Canada

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)

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See PRA Statement below.

510(k) Number *(if known)*
K214001

Device Name
Comprehensive® Shoulder System, Comprehensive® Reverse Shoulder System
(Biomet® Comprehensive® Convertible Glenoid Prostheses)

Indications for Use *(Describe)*

Anatomic Applications

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. Fractures of the proximal humerus, where other methods of treatment are deemed inadequate.
6. Difficult clinical management problems, including cuff arthropathy, where other methods of treatment may not be suitable or may be inadequate.

Reverse Applications
The Comprehensive Reverse Shoulder is indicated for use 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.

Comprehensive Convertible Glenoid Baseplate components are intended for cementless applications with the addition of screw fixation.

Interlok® finish humeral stems are intended for cemented use and the MacroBond® coated humeral stems are intended for press-fit or cemented application. Humeral components with porous coated surface coating are indicated for either cemented or uncemented biological fixation applications.

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)

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Indications for Use

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Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K214001

Device Name
Comprehensive® Shoulder System, Comprehensive® Reverse Shoulder System
(Comprehensive Augmented Glenoid Components, Comprehensive Standard Baseplate, Comprehensive Mini Baseplate, Comprehensive® RSA Baseplates)

Indications for Use *(Describe)*

Biomet Comprehensive Reverse Shoulder products are indicated for use 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.

The Comprehensive Reverse Shoulder is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.

Titanium glenospheres are intended for patients with Cobalt Alloy material sensitivity. The wear of these devices has not been tested but, based on pin on disk testing, the wear rate is inferior to that of cobalt alloy glenospheres. A Cobalt Alloy glenosphere is the recommended component for reverse shoulder arthroplasty patients without material sensitivity to cobalt alloy.

Glenoid components with Hydroxyapatite (HA) coating applied over the porous coating are indicated only for uncemented biological fixation applications. The Glenoid Baseplate components are intended for cementless application with the addition of screw fixation.

Interlok® finish humeral stems are intended for cemented use and the MacroBond® coated humeral stems are intended for press-fit or cemented applications. Humeral components with porous coated surface coating are indicated for either cemented or uncemented biological fixation applications.

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)

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510(k) Summary

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

Contact Person: Aishwarya Pandey
Regulatory Affairs Specialist
Telephone: 574.373.3740
Fax: +1(574)-373-3740

Date: March 15, 2023

Subject Device: **Trade Name:** Comprehensive® Shoulder System, Comprehensive® Reverse Shoulder System
Common Name: Shoulder replacement prosthesis

Classification Name:
- PHX – Shoulder Prosthesis, Reverse Configuration (21 CFR 888.3660)
- KWS - Shoulder joint, metal/polymer, semi-constrained, cemented prosthesis (21 CFR 888.3660)
- PAO - Shoulder joint metal/polymer (+additive) semi-constrained cemented prosthesis (21 CFR 888.3660)
- KWT - Shoulder joint metal/polymer non-constrained cemented prosthesis (21 CFR 888.3650)
- MBF - Shoulder joint metal/polymer/metal Nonconstrained or semi-constrained porous-coated uncemented prosthesis (21 CFR 888.3670)
- HSD – Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis (21 CFR 888.3690)

Predicate Device(s):

Primary Predicate	510(k) Number
Comprehensive Primary Shoulder	K193038
Comprehensive Reverse Shoulder System	K193373
Comprehensive Augmented Baseplates	K172502
Comprehensive Convertible Glenoid	K211729

Device Description
Comprehensive Shoulder System consists of partial and total shoulder replacement components use in cemented and uncemented applications. The devices are modular components consisting of humeral stems, modular heads and glenoid components for anatomic and humeral stem, humeral tray and glenosphere components for reverse configuration application. The purpose of the current submission is to add MR Conditional labeling.

Indications for Use:
Biomet Comprehensive Reverse Shoulder Screws- IFU 01-50-0890
Biomet Comprehensive Reverse Shoulder products are indicated for use 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.

The Comprehensive Reverse Shoulder is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.

Glenoid components with Hydroxyapatite (HA) coating applied over the porous coating are indicated only for uncemented biological fixation applications. The Glenoid Baseplate components are intended for cementless application with the addition of screw fixation.

Interlok® finish humeral stems are intended for cemented use and the MacroBond® coated humeral stems are intended for press-fit or cemented applications. Humeral components with porous coated surface coating are indicated for either cemented or uncemented biological fixation applications.

Biomet® Comprehensive® Reverse Shoulder Products- IFU 01-50-0903
Biomet Comprehensive Reverse Shoulder products are indicated for use 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.

The Comprehensive Reverse Shoulder is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.

Titanium glenospheres are intended for patients with Cobalt Alloy material sensitivity. The wear of these devices has not been tested but based on pin on disk testing, the wear rate is inferior to that of cobalt alloy glenospheres. A Cobalt Alloy glenosphere is the recommended component for reverse shoulder arthroplasty patients without material sensitivity to cobalt alloy.

Glenoid components with Hydroxyapatite (HA) coating applied over the porous coating are indicated only for uncemented biological fixation applications. The Glenoid Baseplate components are intended for cementless application with the addition of screw fixation.

Interlok® finish humeral stems are intended for cemented use and the MacroBond® coated humeral stems are intended for press-fit or cemented applications. Humeral components with porous coated surface coating are indicated for either cemented or uncemented biological fixation applications.

Biomet® Shoulder Joint Replacement Prostheses- IFU 01-50-0944
1.Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2.Rheumatoid arthritis.
3.Correction of functional deformity.
4.Fractures of the proximal humerus, where other methods of treatment are deemed inadequate.
5.Difficult clinical management problems, including cuff arthropathy, where other methods of treatment may not be suitable or may be inadequate.

Optional use in revision: in some medical conditions (e.g.,revision when healthy and good bone stock exists), the surgeon may opt to use primary implants in a revision procedure.

Humeral components with a porous coated surface coating are indicated for either cemented or uncemented biological fixation applications.

The Comprehensive® Modular Hybrid® Glenoid is intended to be implanted with bone cement. The optional porous titanium peg may be inserted without bone cement. The optional polyethylene peg should be inserted with bone cement.

The Comprehensive Humeral Positioning Sleeves are for cemented use only and are intended for use with the Comprehensive Fracture Stem.

The Versa-Dial Humeral Head Prosthesis is intended for use only with the Comprehensive Shoulder Stems (Fracture, Primary and Revision), and the glenoid components of the Comprehensive Shoulder System.

The Titanium Versa-Dial Humeral Head Prosthesis is indicated for patients with suspected cobalt alloy sensitivity. The wear properties of Titanium and Titanium alloys are inferior to that of cobalt alloy. A Titanium humeral head is not recommended for patients who lack suspected material sensitivity to cobalt alloy*

*The Titanium Versa-Dial Humeral Head Prosthesis is not for sale in Canada.

Biomet® Comprehensive® Convertible Glenoid Prostheses- IFU 01-50-1256

Anatomic Applications

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. Fractures of the proximal humerus, where other methods of treatment are deemed inadequate.
6. Difficult clinical management problems, including cuff arthropathy, where other methods of treatment may not be suitable or may be inadequate.

Reverse Applications

The Comprehensive Reverse Shoulder is indicated for use 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.

Comprehensive Convertible Glenoid Baseplate components are intended for cementless applications with the addition of screw fixation.

Interlok® finish humeral stems are intended for cemented use and the MacroBond® coated humeral stems are intended for press-fit or cemented application. Humeral components with porous coated surface coating are indicated for either cemented or uncemented biological fixation applications.

Comprehensive Augmented Glenoid Components, Comprehensive Standard Baseplate, Comprehensive Mini Baseplate (aka Comprehensive® RSA Baseplates)- IFU 01-50-1284

Biomet Comprehensive Reverse Shoulder products are indicated for use 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.

The Comprehensive Reverse Shoulder is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.

Titanium glenospheres are intended for patients with Cobalt Alloy material sensitivity. The wear of these devices has not been tested but, based on pin on disk testing, the wear rate is inferior to that of cobalt alloy glenospheres. A Cobalt Alloy glenosphere is the recommended component for reverse shoulder arthroplasty patients without material sensitivity to cobalt alloy.

Glenoid components with Hydroxyapatite (HA) coating applied over the porous coating are indicated only for uncemented biological fixation applications. The Glenoid Baseplate components are intended for cementless application with the addition of screw fixation.

Interlok® finish humeral stems are intended for cemented use and the MacroBond® coated humeral stems are intended for press-fit or cemented applications. Humeral components with porous coated surface coating are indicated for either cemented or uncemented biological fixation applications.

Summary of Technological Characteristics:

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

- **Intended Use:** Identical to predicate
- **Indications for Use:** Identical to predicate
- **Materials:** Identical to predicate
- **Design Features:** Identical to predicate
- **Sterilization:** Identical to predicate

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  - Evaluation of MR compatibility to support MR Conditional labeling
    - ASTM F2503-20 (Labeling)
    - ASTM F2119-07R13 (Artifact)
    - ASTM F2213-17 (Torque)
    - ASTM F2052-21 (Displacement Force)
    - ASTM F2182-19E02 (RF-heating) – Preliminary Phantom Evaluation
- **Clinical Tests:**
  - None provided

Substantial Equivalence Conclusion

Based on the information contained within this submission, it is concluded that the Comprehensive Shoulder System is substantially equivalent to the identified predicate device.