April 15, 2026

Biomet Orthopedics
Julie Gantenberg
Regulatory Affairs Principal
56 E. Bell Drive
Warsaw, Indiana 46580

Re: K252404
Trade/Device Name: Comprehensive Reverse Shoulder - HA Glenosphere Baseplates
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS
Dated: July 31, 2025
Received: March 16, 2026

Dear Julie Gantenberg:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Farzana Sharmin, PhD.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252404

Device Name
Comprehensive Reverse Shoulder - HA Glenosphere 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 Biomet Comprehensive Reverse Shoulder Products is indicated for primary, fracture, or revision reverse 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 for patients without material sensitivity to cobalt alloy.

Glenoid components with Hydroxyapatite (HA) coating applied over the Ti6Al4V coating are indicated only for uncemented applications. The Glenoid Baseplate components are intended for cementless application with the addition of screw fixation.

Humeral stem components 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.

510(k) #: K252404

510(k) Summary

Prepared on: 2026-03-16

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Biomet Orthopedics
Applicant Address	56 E. Bell Drive Warsaw IN 46580 United States
Applicant Contact Telephone	574-377-8133
Applicant Contact	Ms. Julie Gantenberg
Applicant Contact Email	julie.gantenberg@zimmerbiomet.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Comprehensive Reverse Shoulder - HA Glenosphere Baseplates
Common Name	Shoulder joint metal/polymer semi-constrained cemented prosthesis
Classification Name	Shoulder Prosthesis, Reverse Configuration
Regulation Number	888.3660
Product Code(s)	PHX, KWS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K193373	Comprehensive Reverse Shoulder	PHX
K214001	Comprehensive Shoulder System, Comprehensive Reverse Shoulder System	PHX
K080642	Comprehensive Reverse Shoulder	PHX
K120121	Comprehensive Reverse Shoulder - Mini Baseplate	PHX
K172502	Comprehensive Augmented Glenoid Baseplate	PHX

Device Description Summary

21 CFR 807.92(a)(4)

The Comprehensive Reverse Shoulder System (CRS) is a total shoulder replacement system in a reverse configuration. The CRS system is composed of Humeral Trays, Humeral Bearings, Glenospheres, Taper Adaptor, Glenosphere Baseplate, Central Screws, Fixed Locking, Non-Locking, and Variable Locking Screws. The purpose of the current 510(k) notification is to make a change to the manufacturing/ materials of the existing Standard and Mini Glenosphere Baseplate components, specifically moving to a different manufacturing site and proposing a different vendor for the application of the Hydroxyapatite (HA) coating. No changes are proposed to any of the other components of the system.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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 Biomet Comprehensive Reverse Shoulder Products is indicated for primary, fracture, or revision reverse 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 for patients without material sensitivity to cobalt alloy.

Glenoid components with Hydroxyapatite (HA) coating applied over the Ti6Al4V coating are indicated only for uncemented applications. The Glenoid Baseplate components are intended for cementless application with the addition of screw fixation.

Humeral stem components are indicated for either cemented or uncemented biological fixation applications.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use are identical to the primary predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

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

- Intended Use: Identical to predicate device
- Indications for Use: Identical to predicate device
- Materials: Similar to the predicate
- Design Features: Identical to predicate device
- Packaging: Similar to predicate device
- Sterilization: Identical to reference device

Note: Regarding Materials, the baseplate substrate material is identical to the predicate. The subject HA Coating is similar to predicate.The underlying PPS Coating is identical to the reference device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

A Biocompatibility assessment, Shelf-life Study, and Characterization of the dual (HA/PPS) coating of the Comprehensive Glenosphere Baseplate components were conducted in support of substantial equivalence.

Characterization was performed on devices and coupons after final cleaning and gamma sterilization and met all applicable acceptance criteria.

Physicochemical, Microstructure, and Mechanical Testing analyses were done using the worst-case thickness and the NIST (SRM) 2910b control as recommended by the draft 2024 FDA guidance. Dual (HA/PPS) Coating characterization analyses included:

- Elemental analysis;
- Phase Analysis;
- Ca/P ratio analysis,
- Infrared analysis (FTIR);
- Dissolution rate;
- Microstructure
  - o Coating pore size
  - o Volume porosity
  - o Coating thickness
  - o Interconnecting porosity
- Static tensile;
- Shear fatigue;

The non-clinical testing demonstrates that the proposed coating of the Comprehensive Standard and Mini Glenosphere Baseplate components establish substantially equivalence to the predicate device.