June 16, 2026

Zimmer, Inc.
Eric Van Horn
Principal, Regulatory Affairs
1800 W. Center St.
Warsaw, Indiana 46580

Re: K261683
Trade/Device Name: Augment Off-Axis Instrument 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, KWT
Dated: May 21, 2026
Received: May 21, 2026

Dear Eric Van Horn:

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,

Joseph P. Russell -S

for: 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261683

Please provide the device trade name(s).

Augment Off-Axis Instrument System

Please provide your Indications for Use below.

The Augment Off-Axis Instrument System consists of specialized instruments intended to prepare anatomy prior to implantation of Comprehensive® Reverse Shoulder System components in reverse total shoulder arthroplasty procedures or Alliance® Augmented Glenoid System components in anatomic total shoulder arthroplasty procedures in accordance with their respective cleared indications for use and contraindications.

The instruments for this system are specifically indicated for use with the Comprehensive ® Reverse Shoulder System (K193373) or the Alliance® Augmented Glenoid System (K193180).

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) #: K261683

510(k) Summary

Prepared on: 2026-05-21

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Zimmer,Inc.
Applicant Address	1800 W Center Street Warsaw IN 46580 United States
Applicant Contact Telephone	765-336-9090
Applicant Contact	Mr. Eric Van Horn
Applicant Contact Email	eric.vanhorn@zimmerbiomet.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Augment Off-Axis Instrument System
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, KWT

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K241043	Augment Off-Axis Instrument System	PHX

Device Description Summary

21 CFR 807.92(a)(4)

There are no changes to the device description from the previously cleared Augment Off-Axis Instrument System predicate device (K241043). The Subject 510(k) describes minor changes to the design and labeling as a result of investigations into complaints. These changes are intended to be effected immediately upon submission acknowledgment.

The Augment Off-Axis Instrument System consists of specialized instruments that are designed for preparation of anatomy prior to implantation of Comprehensive® Reverse Shoulder System or Alliance® Augmented Glenoid System components. The instruments in this system are intended to provide an alternate approach in ensuring proper preparation of the glenoid bone and tissue for receipt of a glenoid implant augment in reverse and anatomic total shoulder arthroplasty procedures.

A drop-in instrument tray contains the Augment Off-Axis reusable surgical instruments for secure and ergonomic storage, sterilization, and transportation between uses.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Augment Off-Axis Instrument System consists of specialized instruments intended to prepare anatomy prior to implantation of Comprehensive® Reverse Shoulder System components in reverse total shoulder arthroplasty procedures or Alliance® Augmented Glenoid System components in anatomic total shoulder arthroplasty procedures in accordance with their respective cleared indications for use and contraindications.

The instruments for this system are specifically indicated for use with the Comprehensive ® Reverse Shoulder System (K193373) or the Alliance® Augmented Glenoid System (K193180).

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

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

Technological Comparison 21 CFR 807.92(a)(6)

The subject device is substantially equivalent to the predicate in design features, intended use, materials, dimensions, and function.

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

No Non-Clinical and/or Clinical Tests were submitted to determine the substantial equivalence of the subject device with the predicate.

Verification

The following sections are complete:
Application/Submission Type
Cover Letter / Letters of Reference
Administrative Information
Device Description
Indications for Use
Classification
Predicates and Substantial Equivalence
Benefits, Risks, and Mitigation Measures
Labeling
Reprocessing, Sterility, and Shelf-Life
Biocompatibility
Software/Firmware, Cybersecurity, and Interoperability
EMC, Wireless, Electrical, Mechanical, and Thermal Safety
References
Administrative Documentation

Export Data	If you want to save the data in this eSTAR in XML format, you can click the Export Data button to the left. Your 13 attachments will not be included in the XML file.
Import Data	You can import the XML data of another eSTAR into this eSTAR by clicking the Import Data button to the left, and choosing the XML file. Attachments will not be imported.
Admin Functions	FOR ADMINISTRATOR USE ONLY

Registration and Listing

Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States (U.S.) are required to register annually with the FDA. This process is known as establishment registration.

Congress has authorized FDA to collect an annual establishment registration fee for device establishment registrations. A detailed list of all those establishment types that have to pay the registration fee can be found at the Who Must Register, List and Pay the Fee website. There are no reductions in annual establishment registration fees for small businesses or any other group.

Most establishments that are required to register with the FDA are also required to list the devices that are made there and the activities that are performed on those devices. If a device requires premarket approval or notification before being marketed in the U.S., then the owner/operator should also submit the FDA premarket submission number (510(k), De Novo, PMA, PDP, HDE). The owner/operator cannot list the device until the premarket submission has been cleared, granted, or approved to market in the United States.

Registration and listing provides FDA with the location of medical device establishments and the devices manufactured at those establishments. Knowing where devices are made increases the nation's ability to prepare for and respond to public health emergencies.

For details about registering and listing your device, please see the Device Registration and Listing website. If you encounter an issue or wish to contact us regarding the Electronic Registration and Listing System known as the FDA Unified Registration and Listing System (FURLS)/Device Registration and Listing Module (DRLM), please send an email to reglist@cdrh.fda.gov.