August 15, 2025

Zimmer Biomet
Courtney Williams
Regulatory Affairs Specialist
1800 W. Center Street
Warsaw, Indiana 46580

Re: K251834
Trade/Device Name: Persona Partial Knee
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSX
Dated: June 13, 2025
Received: June 16, 2025

Dear Courtney Williams:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2025.08.15 16:27:25 -04'00'

For Lixin Liu, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K251834

Device Name

Persona Partial Knee

Indications for Use *(Describe)*

The Persona Partial Knee system is limited to the medial tibiofemoral compartment of the knee intended for patients with painful and/or disabling knee joints due to the following indications:

- Noninflammatory degenerative joint disease (NIDJD), e.g., osteoarthritis, avascular necrosis;

- traumatic arthritis;

- previous tibial condyle or plateau fractures with loss of anatomy or function;

- varus deformities; and

- revision of the articular surface of a previously implanted Persona Partial Knee System providing that the tibial plate locking mechanism is not compromised and the femoral and tibial plate components remain well fixed and undamaged.

The Persona Partial Knee System is a single use implant intended for implantation with bone cement.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Sponsor:
Biomet Inc
56 East Bell Drive
Warsaw
Indiana
46581
USA
Establishment Registration Number: 1825034

Contact Person:
Courtney Williams
Regulatory Affairs Specialist
Telephone: +44 (0)7378413306
Courtney.williams@zimmerbiomet.com

Date: April 17, 2025

Subject Device: **Trade Name:** *Persona® Partial Knee*

Primary Regulation Name: 21 CFR 888.3520 - Knee joint femorotibial metal/polymer non-constrained cemented prosthesis

Product Code: HSX (Class 2) - Prosthesis, Knee, Femorotibial, Non-Constrained, Cemented, Metal/Polymer

Predicate Device(s):

510(k) Number(s)	***Device Name***	***Applicant***
K161592	*Persona® Partial Knee*	Biomet Orthopedics

Device Description:

The purpose of this submission is to add a line extension of Size B to the Persona Partial Knee system (PPK). The Persona Partial Knee System is a partial knee replacement for the medial compartment of the knee and is modular in design consisting of three components: a unicondylar cobalt-chromium-molybdenum (Co-Cr-Mo) alloy femoral

component, a unicondylar titanium (Ti-6Al-4V) alloy tibial tray, and a unicondylar articular surface manufactured using the previously cleared Vivacit-E ® Vitamin-E Highly Crosslinked Polyethylene (VEHXPE).

Indications for Use:

The Persona Partial Knee system is limited to the medial tibiofemoral compartment of the knee intended for patients with painful and/or disabling knee joints due to the following indications:

- Noninflammatory degenerative joint disease (NIDJD), e.g., osteoarthritis, avascular necrosis;
- Traumatic arthritis;
- Previous tibial condyle or plateau fractures with loss of anatomy or function;
- Varus deformities; and,
- Revision of the articular surface of a previously implanted Persona Partial Knee System providing that the tibial plate locking mechanism is not compromised and the femoral and tibial plate components remain well fixed and undamaged.

The Persona Partial Knee System is a single use implant intended for implantation with bone cement.

Summary of Technological Characteristics:

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

- **Intended Use:** Identical as the predicate device.
- **Indications for Use:** Identical as the predicate device.
- **Variants/Sizes:** Similar as the predicate device.
- **Design Features:** Similar to the predicate device
- **Material:** Identical as the predicate device
- **Sterility:** Identical as the predicate device.
- **Shelf Life:** Identical as the predicate device.

Summary of Performance Data (Nonclinical and/or Clinical):

The performance data provided in the performance testing section indicate the proposed devices meet the established acceptance criterion; therefore, are as safe

and effective and substantially equivalent to the legally marketed predicate devices from a performance standpoint.

Substantial Equivalence Conclusion:

The subject device, *Persona® Partial Knee*, has similar size and design features to the predicate device. Similarly, the subject device has an identical Indications for Use, Shelf-life, intended use, materials of construction, performance, and sterility as its predicate device. Therefore the *Persona® Partial Knee* (K161592) and the information provided demonstrates:

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