October 29, 2024

Zimmer, Inc.
Gregory Foster
Regulatory Affairs Principal
1800 W. Center Street
Warsaw, Indiana 46580

Re: K243247
Trade/Device Name: Persona the Personalized Knee System
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH, OIY
Dated: October 11, 2024
Received: October 11, 2024

Dear Gregory Foster:

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,

Lixin Liu -S

Lixin Liu, 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)*
K243247

Device Name
Persona® the Personalized Knee System

Indications for Use *(Describe)*
When a mechanical alignment approach is utilized, this device is indicated for patients with severe knee pain and disability due to:
-Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Collagen disorders, and/or avascular necrosis of the femoral condyle.
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy.
- Moderate valgus, varus, or flexion deformities.
- The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery.

When a Personalized Alignment approach is utilized, this device is indicated for patients with severe knee pain and disability due to:
- Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Collagen disorders, and/or avascular necrosis of the femoral condyle.
- Moderate valgus, varus, or flexion deformities.

The Personalized Alignment (PA) surgical technique may only be used with Persona cemented and uncemented CR femoral components, Persona CR, Ultra Congruent (UC), and Medial Congruent (MC) articular surface components, the Persona Cemented Stemmed tibial components without a stem extension, and the Persona OsseoTi Keel Tibia and Cemented Keel Tibia.

Porous coated components may be used cemented or uncemented (biological fixation), except for the Persona OsseoTi Keel Tibia and the Persona OsseoTi 3-peg Patella which are for uncemented use only. All other femoral, tibial baseplate and all-polyethylene (UHMWPE and VEHXPE) patella components are indicated for cemented use only.

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) Summary

**Sponsor:**

Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708
Establishment Registration Number: 1822565

**Contact Person**:

Gregory Foster
Regulatory Affairs Principal
Telephone: (574) 371-0519
Fax: fax (574) 377-3718
Gregory.foster@zimmerbiomet.com

**Date:**

October 28, 2024

**Subject Device:**

**Trade Name:** Persona® the Personalized Knee System

**Common Name: Knee Prosthesis**

**Classification Name:**

**Classification Name:**

- MBH - Prosthesis, Knee, Patello/Femorotibial, Semi-Constrained, Uncemented, Porous, Coated, Polymer/Metal/Polymer (21 CFR 888.3565 Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis)
- JWH – Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer (21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis)
- OIY- Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer + Additive/Metal/Polymer + Additive (21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

**Predicate/Reference Device(s):**

| | | | |
|---|---|---|---|
| Primary Predicate | K240299 | Zimmer® Persona® the Personalized Knee System: Persona OsseoTi 3-Peg Patella | Zimmer, Inc. |
| Reference Device | K031462 | NexGen® Primary Porous Patella | Zimmer, Inc. |

**Device Description:**

The purpose of this submission is to add compatibility of the Persona OsseoTi 3-Peg Patella to the Persona® the Personalized Knee System Posterior Stabilized (PS) femoral components. The addition of this compatibility does not change the intended use or fundamental scientific technology of the device system.

The Persona® the Personalized Knee System is a semiconstrained modular knee prosthesis designed to resurface the articulating surface of the femoral, tibial, and patella bones. With this submission compatibility of the Persona OsseoTi 3-Peg patella components will be added to the Persona PS femoral components of the knee system. These patella components articulate against femoral component as part of a total knee system. These patellar components come in a variety of sizes to match the needs of a patient's anatomy when performing total knee arthroplasty. These components are provided sterile and single use.

**Indications for Use:**

When a mechanical alignment approach is utilized, this device is indicated for patients with severe knee pain and disability due to:
-Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Collagen disorders, and/or avascular necrosis of the femoral condyle.
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy.
- Moderate valgus, varus, or flexion deformities.
- The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery.

When a Personalized Alignment approach is utilized, this device is indicated for patients with severe knee pain and disability due to:
- Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Collagen disorders, and/or avascular necrosis of the femoral condyle.
- Moderate valgus, varus, or flexion deformities.

The Personalized Alignment (PA) surgical technique may only be used with Persona cemented and uncemented CR femoral components, Persona CR, Ultra Congruent (UC), and Medial Congruent (MC) articular surface components, the Persona Cemented Stemmed tibial components without a stem extension, and the Persona OsseoTi Keel Tibia and Cemented Keel Tibia.

Porous coated components may be used cemented or uncemented (biological fixation), except for the Persona OsseoTi Keel Tibia and the Persona OsseoTi 3-peg Patella which are for uncemented use only. All other femoral, tibial baseplate and all-polyethylene (UHMWPE and VEHXPE) patella components are indicated for cemented use only.

**Indications for Use Comparison:** The indications for Use are identical between the predicate and the subject device.

**Technological Comparison:** The subject and predicate devices are identical metal-backed porous patella resurfacing prostheses, with a direct compression molded UHMWPE articulating surface. The articulating geometry are identical between the predicate and the subject devices. The difference is that the predicate is only compatible with the CR femoral variants of the Persona the Personalized Knee System, while the subject device is compatible with both the PS and CR variants of the femoral components.

**Non-Clinical and/or Clinical Tests (Summary & Conclusions):**

- **Non-Clinical Tests:**
  - Durability Testing, per ISO 14243-5, Persona OsseoTi 3-Peg Patella with Size 9 PS Femur
  - Durability Testing, per ISO 14243-5, Persona OsseoTi 3-Peg Patella with Size 12 PS Femur
  - Durability Performance of the NexGen TM Patella per ISO 14243-5
  - Durability Testing, per ISO 14243-5, 35 mm NexGen TM Patella with SZ 12 PS Femur

- **Clinical Tests:**
  None provided

The proposed device has the same intended use as the predicate(s). The proposed device has identical technological characteristics to the predicate(s), 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 device(s).

**Substantial Equivalence Conclusion:** Based on the information contained within this submission, it is concluded that the Persona® the Personalized Knee System are substantially equivalent to the identified predicate device.