May 28, 2026

Zimmer Inc.
Dora Hu
Senior Regulatory Affairs Specialist
1800 W. Center Street
Warsaw, Indiana 46580

Re: K251840
Trade/Device Name: Zimmer® Persona® 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: May 1, 2026
Received: May 1, 2026

Dear Dora Hu:

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,

LIXIN LIU -S

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

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.	K251840

Please provide the device trade name(s).

Zimmer® Persona® Personalized Knee System

Please provide your Indications for Use below.

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 AlignmentTM* 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 which is for uncemented use only. All other femoral, tibial baseplate and all-polyethylene (UHMWPE and VEHXPE) patella components are indicated for cemented use only.
*Check for country clearances of the Persona Personalized Alignment surgical technique; not licensed in the European Union

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K251840

510(k) Summary

Prepared on: 2026-05-28

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	+86 18892625295
Applicant Contact	Ms. Dora Hu
Applicant Contact Email	Dora.Hu@zimmerbiomet.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Zimmer® Persona® Personalized Knee System
Common Name	Total Knee System
Classification Name	Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulation Number	888.3565
Product Code(s)	MBH, JWH, OIY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K221479	Persona® Personalized Knee System	JWH, MBH,

Device Description Summary

21 CFR 807.92(a)(4)

The purpose of this submission is to add an alternative Porous Plasma Spray coating vendor DOT America and update MR conditional labeling for the subject Persona® Personalized Knee System components: Persona Porous Plasma Spray (PPS) Femoral Components.

The Persona Knee System resurfaces the articulating surfaces of the femur, tibia, and patella bones. The femoral components are used in combination with the existing Persona articular surfaces (required), an existing Persona tibial baseplate (required), and an optional, existing, Persona patellar component in total knee replacement surgery.The Persona femoral components articulate against the articular surfaces with or without an intact PCL, depending on configuration and patient need. They have highly polished condyles to minimize wear with the mating articular surfaces. They are able to safely accommodate high flexion of up to 155°, which is dependent upon the selected type of articular surface and femoral component. Conformity is achieved through the interaction of the femoral condyles with the articular surface. The femoral components are designed to articulate against a resurfaced or a non-resurfaced patella.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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 AlignmentTM* 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 which is for uncemented use only. All other femoral, tibial baseplate and all-polyethylene (UHMWPE and VEHXPE) patella components are indicated for cemented use only.
*Check for country clearances of the Persona Personalized Alignment surgical technique; not licensed in the European Union

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

The subject device has the same intended use as the predicate devices and the same indications for use as the predicate devices.

Technological Comparison 21 CFR 807.92(a)(6)

The intended use, materials, design, packaging and sterilization method of the Persona the Personalized Knee System are unchanged since last 510(k) clearance (K221479). The proposed change is to add an alternate vendor to perform the porous plasma spray coating process to the Persona Porous Plasma Spray (PPS) femoral components. The PPS coating, supplied by this and the predicate's vendor meets the specifications for the design of the subject device.
The proposed device has similar technological characteristics to the predicate, 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.

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

Non-Clinical Tests:
• Posterior Condyle Fatigue Testing
• Porous Plasma Spray Coating Product Requirements
• Porous Plasma Spray Coating Product Design Verification Requirements
• Biocompatibility
• Expanded MRI Compatibility Evaluation for the Persona Primary Knee System

Clinical Tests:
No clinical testing was required to support substantial equivalence.

Conclusion:
Non-clinical testing demonstrated that the subject devices are substantially equivalent to the predicate devices.