March 6, 2025

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

Re: K243724
Trade/Device Name: Persona® Revision Knee System (Persona Revision SoluTion™ Femoral Components)
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH, MBH, OIY
Dated: December 3, 2024
Received: February 10, 2025

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, 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)*

K243724

Device Name

Persona® Revision Knee System (Persona Revision SoluTion™ Femoral Components)

Indications for Use *(Describe)*

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.

Porous components may be used cemented or uncemented (biological fixation). Augments may be attached via bone cement or screw to the tibial plates and/or femoral components. Splined stem extension components are intended to be used press-fit (uncemented). All other femoral component, tibial plate, stem extension, and femoral and tibial augment 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K243724

510(k) Summary

Prepared on: 2025-03-05

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	(574) 371-0519
Applicant Contact	Dr. Gregory Foster
Applicant Contact Email	gregory.foster@zimmerbiomet.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Persona® Revision Knee System (Persona Revision SoluTion™ Femoral Components)
Common Name	Knee Prosthesis
Classification Name	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulation Number	888.3560; 888.3565
Product Code(s)	JWH, MBH, OIY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K181947	Persona® Revision Knee System	JWH, MBH,
K200209	Persona® Personalized Knee System	JWH, OIY

Device Description Summary

21 CFR 807.92(a)(4)

The purpose of this submission is to add a new component to the Persona Revision Knee System, the component is the Persona Revision SoluTion Femoral Components. The addition of these components do not change the intended use or fundamental scientific technology of the device system.

The Persona Revision Knee System is a semiconstrained modular knee prosthesis designed to resurface the articulating surface of the femoral and tibial bones. With this submission a new Ti-6Al-4V femoral component will be added to the system. These femoral components articulate against an articular surface of the tibial component, as well as, a patellar component, as part of a total knee system. The new femoral components are compatible with a variety of augments, cones, and stem extensions and 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.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

Porous components may be used cemented or uncemented (biological fixation). Augments may be attached via bone cement or screw to the tibial plates and/or femoral components. Splined stem extension components are intended to be used press-fit (uncemented). All other femoral component, tibial plate, stem extension, and femoral and tibial augment components are indicated for cemented use only.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Indications for Use are Identical between the Subject and Predicate devices.

Technological Comparison

21 CFR 807.92(a)(6)

The subject and predicate devices are both femoral components. The articulating geometry are equivalent between the predicate and the subject devices. The difference is that the predicate is manufactured with Co-Cr-Mo alloy, while the subject device is manufactured with forged Ti-6Al-4V and undergoes the Ti-Nidium™ nitrogen surfacing hardening process.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Anterior Flange Fatigue Evaluation of the Persona Revision SoluTion Femoral Components.
Posterior Condyle Fatigue Evaluation of the Persona Revision SoluTion Femoral Components.
In Vitro Wear Evaluation of the Persona SoluTion Revision Femoral Components Coupled with Persona Revision Vivacit-E and Persona Primary PS and CPS Vivacit-E Bearings.
In Vitro 3BW and Roughened Femoral Evaluation of the Persona Revision SoluTion Femoral Components.
Persona Revision SoluTion Femur Constraint, Range of Motion (ROM), Contact Area, and Contact Stress Assessment.
Persona Revision SoluTion Femur Augment Shear.
Persona SoluTion Revision Femur Augment Torque.
Persona Revision TiNidium (SoluTion) Stem Junction Fatigue
Persona Revision SoluTion Femur Stem Static Axial Pull-Off
Persona Revision SoluTion Femur Stem Static Torque-Off.
Expanded In-Vivo RF-Induced Heating Simulations for the Persona Revision Knee System (which included analysis of magnetically induced displacement force and torque).
Persona Revision SoluTion Femur Fretting Corrosion Assessment.

Clinical Testing Not Applicable

The proposed device has the same intended use as the predicate(s). The proposed device has similar 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).