September 28, 2021

Zimmer Switzerland Manufacturing GmbH
Anne-Kathrin Born
Regulatory Affairs Senior Specialist
Sulzerallee 8
Winterthur, Zurich 8404
SWITZERLAND

Re: K212129/S001
Trade/Device Name: Persona® Personalized Knee System
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, OIY, MBH
Dated: September 8, 2021
Received: September 10, 2021

Dear Anne-Kathrin Born:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Ting Song, Ph.D., R.A.C.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212129

Device Name
Persona® 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 kinematic 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 kinematic alignment (KA) surgical technique may only be used with Persona CR femoral components, Persona CR or UC articular surface components, and cemented nonporous Persona tibial components without a stem extension.

Porous coated components may be used cemented or uncemented (biological fixation). 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 Switzerland Manufacturing GmbH Sulzerallee 8, P.O. Box 8404 Winterthur, Switzerland
Contact Person:	Anne-Kathrin Born Senior Specialist, Regulatory Affairs Telephone: +41 79 518 26 17 Fax: +41 52 244 86 58
Date:	September 28, 2021
Trade Name:	Persona® Personalized Knee System
Common Name:	Knee Prostheses
Classification:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (21CFR 888.3560) Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis (21 CFR 888.3565)
Product Codes:	JWH, OIY, MBH
Predicate Device:	Zimmer Persona™ Knee System, manufactured by Zimmer Inc., K113369, cleared March 27, 2012
Device Description:	The Persona Personalized Knee System is a semiconstrained modular knee prosthesis designed to resurface the articulating surface of the femoral, tibial and patellar bones. The Persona Personalized Knee System includes surgical instrumentation that facilitate implantation of the above described implant components. The purpose of this submission is the introduction of an optional alternative surgical technique for distal femoral resection that enables for gap balancing and femoral external rotation, accomplished via the use of a new instrument platform including a femoral rotation guide and anterior-posterior cutting blocks. The resection of the proximal tibia is performed in accordance with the standard Persona Primary Knee Surgical Technique. The new instruments do not change the intended use or fundamental scientific technology of the Persona Personalized Knee System components.
Intended Use and 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 kinematic 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 kinematic alignment (KA) surgical technique may only be used with Persona CR femoral components, Persona CR or UC articular surface components, and cemented nonporous Persona tibial components without a stem extension.

Porous coated components may be used cemented or uncemented (biological fixation). All other femoral, tibial baseplate, stem extension, and all-polyethylene (UHMWPE and VEHXPE) patella components are indicated for cemented use only.

Comparison to Predicate Device:

The subject instruments do not change the intended use or the fundamental scientific technology of the existing instruments used with the Persona Personalized Knee System.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

- Biocompatibility assessment
- Cadaveric design validation
- Design Verification Modular Brackets

Clinical Performance and Conclusions:

- Clinical data and conclusions were not needed for this device.

Conclusion:

The subject devices have the same intended use and indications for use as the predicate devices. The subject devices use the similar operating principle, incorporate the same basic design and labeling and are manufactured and sterilized using the similar materials and processes as the predicate devices.

Except for the modifications described in this submission the subject devices are identical to the predicate devices, and the performance data and analyses demonstrate that:

- any differences do not raise new questions of safety and effectiveness as established with performance testing; and
- the subject devices are at least as safe and effective as the legally marketed predicate devices.