March 8, 2023

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

Re: K230321
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, MBH, OIY
Dated: February 3, 2023
Received: February 6, 2023

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 (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 -S

Ting Song, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230321

Device Name
Zimmer® 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 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 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.

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
Sr. Regulatory Specialist
Telephone: (574) 371-0519
Fax: fax (574) 377-3718
Gregory.foster@zimmerbiomet.com

Date:

03-Feb-2023

Subject Device:

Trade Name: Persona® Personalized Knee System

Common Name: Knee Prosthesis

Classification Name:

Classification Name:

- JWH – Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer (21 CFR 888.3560)
- MBH - Prosthesis, Knee, Patello/Femorotibial, Semi-Constrained, Uncemented, Porous, Coated, Polymer/Metal/Polymer (21 CFR 888.3565)
- OIY- Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer + Additive/Metal/Polymer + Additive (21 CFR 888.3560)

Predicate Device(s):

K113369	Zimmer® Persona™ Knee System	Zimmer, Inc.
K172524	Zimmer® Persona™ Knee System	Zimmer, Inc.
K221479	Zimmer® Persona™ Knee System	Zimmer, Inc.

Device Description:

The purpose of this submission is to add the Personalized Alignment surgical technique indication to the Persona Personalized Knee System

components: The Persona 0° Cemented Keel Tibia Baseplate and the Persona 0° OsseoTi Spiked Keel Tibia Baseplate. These components consist of a non-porous cemented stemmed tibial baseplate, and a porous OsseoTi™ non-cemented tibial baseplate. The change in indication does not change the intended use or fundamental scientific technology of the device system.

The Persona Personalized Knee System is a semiconstrained modular knee prosthesis designed to resurface the articulating surface of the femoral, tibial, and patellar bones. A femoral component articulates against tibial and patellar articular surfaces to form a total knee system. All of the new 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 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.

Summary of Technological

Characteristics:

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

- **Intended Use:** Identical to the predicate
- **Indications for Use:** Similar to the predicate
- **Materials:** Identical to the predicate
- **Design Features:** Identical to the predicate
- **Sterilization:** Identical to the predicate

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  - Persona® 0° Keel Tibial and Persona® PPS® Femur Design Validation – Device Comparison.
  - Persona 0° Tibia Keel and Peg Perforation Personalized Alignment
- **Clinical Tests:**
  - None provided

Substantial Equivalence Conclusion

Based on the information contained within this submission, it is concluded that the Persona® Personalized Knee System are substantially equivalent to the identified predicate devices.