November 17, 2022

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

Re: K221479
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: October 17, 2022
Received: October 18, 2022

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)*
K221479

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 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 porous and cemented non-porous CR femoral components, Persona CR or UC articular surface components, and the cemented nonporous Persona Natural cemented 5 degree tibial components without a stem extension,

Porous coated components may be used cemented or uncemented (biological fixation), except for the Persona porous 0 degree OsseoTi Spiked 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: 14-Nov-2022

Subject Device:

Trade Name: Persona® Personalized Knee System

Common Name: Knee Prosthesis

Classification Name:

- JWH – Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3560)
- MBH - Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis (21 CFR 888.3565)
- OIY- Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3560)

Predicate Device(s):

K113369	Zimmer® Persona™ Knee System	Zimmer, Inc.
K122745	Zimmer® Persona™ Knee System	Zimmer, Inc.
K173417	Zimmer® Persona™ Knee System	Zimmer, Inc.
K113550	Vanguard Complete Knee System	Biomet, Inc.
K140669	G7 OsseoTi™ Acetabular Shells	Biomet, Inc.
K936159	Natural Knee II System	Zimmer, Inc.

Device Description:

The purpose of this submission is to add three new components to the Persona Personalized Knee System. These components consist of a non-porous cemented stemmed tibial baseplate, a porous OsseoTi™ non-cemented tibial baseplate, and a porous plasma sprayed femur. The addition of these components do 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. With this submission a new porous plasma sprayed femoral component will be added to the system. These femoral components articulate against tibial and patellar articular surfaces to form a total knee system. In addition, two new tibial plates will be added, a cemented non-porous stem tibial baseplate and a porous OsseoTi™ stemmed tibial baseplate. 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. To aid the implantation of these devices several new reusable instruments are also introduced.

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 porous and cemented non-porous CR femoral components, Persona CR or UC articular surface components, and the cemented nonporous Persona Natural cemented 5 degree tibial components without a stem extension,

Porous coated components may be used cemented or uncemented (biological fixation), except for the Persona porous 0 degree OsseoTi Spiked 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 and similar to the predicate
- **Sterilization:** Identical to the predicate

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  - Posterior condyle fatigue testing per internal test methods.
  - Anterior flange fatigue testing per an internal test method.
  - Evaluation of porous plasma spray (PPS) coating.
  - Evaluation of OsseoTi porous structure.
  - Fatigue strength of the Persona 0° Cemented Keel Tibial Baseplate per ASTM F1800 and ISO 14879-1.
  - Fatigue strength of the Persona 0° Spiked Keel Tibial Baseplate per ASTM F1800 and ISO 14879-1.
  - Evaluation of the level of micromotion of the Persona 0° OsseoTi tibial baseplate per an internal test method.
  - Fixation performance of the Persona 0° Cemented Keel Tibia per an internal test method.
  - Analysis of keel and peg drill perforation rate.
  - Assessment of MR compatibility.
  - Bacterial Endotoxin Test (BET) per ANSI/AAMI ST 72:2011as part of cleaning validation demonstrating implants meet the limit of ≤20 Endotoxin units (EU)/Device per USP41-NF36 Chapter <161> Medical Devices – Bacterial Endotoxin and Pyrogen Tests.

- **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.