January 24, 2020

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

Re: K193223
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
Dated: November 21, 2019
Received: November 22, 2019

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
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193223

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.

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

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510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Persona® Personalized Knee System 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor:

Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708
Establishment Registration Number: 1822565

Contact Person:

Gregory Foster
Specialist, Regulatory Affairs
Telephone: 574-371-0519
Fax: 574-372-4710

Date:

20-Jan-2020

Subject Device:

Trade Name: Persona® Personalized Knee System
Common Name: Knee Prosthesis

Classification Name:

- JWH – Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer (21 CFR 888.3560)
- 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.
K062768	NexGen® Complete Knee Solution Legacy® Posterior Stabilized Flex Fixed Bearing and Tivanium® Ti-6Al-4V Alloy Femoral	Zimmer, Inc.
K172524	Zimmer® Persona® The Personalized Knee System	Zimmer, Inc.

Purpose and Device Description:	The purpose of this submission is for the addition of the Ti-Nidium cruciate retaining (CR) femoral components to the Persona Personalized Knee System. These modifications do not change the intended use or fundamental scientific technology of the device. 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, femoral components made from Titanium alloy (ASTM F136) that undergo the Ti-Nidium nitriding surface hardening treatment are being added to the system. These femoral components articulate against tibial and patellar articular surfaces to form a total knee system. This design is available in multiple sizing options to accommodate a wide range of anatomies. "Narrow" femoral components have a smaller M/L dimension than the "Standard" femoral components. This femoral component, when used with a CR or Medial Congruent (MC) articular surface, can accommodate a maximum active flexion of 155°, and with an Ultra Congruent (UC) articular surface, can accommodate a maximum active flexion of 145°. These femoral components are provided sterile and single use.
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, 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 predicates.
- **Indications for Use:** Identical to predicate.
- **Materials:** Similar to predicates.
- **Design Features:** Identical to predicate
- **Sterilization:** Identical to predicate.

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  - Intercondylar (IC) notch deformation testing per an internal test method.
  - Posterior condyle fatigue testing per an internal test method.
  - Ti-Nidium femoral induced wear of ultra-high molecular weight polyethylene (UHMWPE) articular surfaces testing per ISO 14243-3.
  - Assessment of wear due to 3rd body particles during articulation.

- Evaluation of the Persona Ti-Nidium Femur Components in the Magnetic Resonance Imaging (MRI) Environment.

- 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:**
  - Clinical data was not deemed necessary for the subject device.

Substantial Equivalence Conclusion

The subject device has the same intended use and indications for use as the predicate devices. The subject device has similar technological characteristics to the predicates, and the performance data and analyses demonstrate that:

- any differences do not raise new questions of safety and effectiveness; and
- the proposed device is at least as safe and effective as the legally marketed predicate devices.