September 5, 2019

Zimmer Inc.
Nicole Meredith
Regulatory Project Manager
1800 W. Center Street
Warsaw, Indiana 46580

Re: K191625
Trade/Device Name: Persona Revision Knee System
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH, OIY
Dated: June 14, 2019
Received: June 18, 2019

Dear Nicole Meredith:

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,

For Ting Song, Ph.D.
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)*
K191625

Device Name
Persona® Revision Knee System

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) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Persona Revision 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.
1800 W. Center Street
Warsaw, IN 46580
Establishment Registration Number: 1822565

Contact Person:

Nicole J. Meredith
Regulatory Affairs Project Manager
Telephone: (574) 377-3718
Fax: (574) 372-4710

Date:

August 19, 2019

Subject Device:

Trade Name: Persona® Revision Knee System

Common Name: Knee Prosthesis

Classification Name:

- MBH – Prosthesis, Knee, Patello/Femorotibial, Semi-Constrained, Uncemented, Porous, Coated, Polymer/Metal/Polymer (21 CFR 888.3565)
- 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 Devices:

Persona Revision Knee System	K181947
Natural-Knee II System	K173057 K013031 K982903 K972501

Purpose and Device Description:

The purpose of this submission is for modifications to the Persona Revision stem extensions, several instruments, and the associated case components of the Persona Revision Knee System. These modifications do not change the intended use or fundamental scientific technology of the device.

The Persona Revision Knee System is a semi-constrained total knee prosthesis consisting of anatomically shaped components designed to resurface the articulating surface of the femoral and tibial bones including:

- Femoral components
- Articular surfaces
- Tibial components
- Stem extensions
- Femoral and tibial augments
- Femoral and tibial cones

The large modularity of the componentry of the Persona Revision knee system including articular surfaces with different levels of constraint, augments, cones and stem extensions provides numerous possible configurations to optimally address the bone and joint condition of the patient in a primary or revision TKA surgery.

The Persona Revision Knee System also includes non-implantable tools, or instrumentation, that facilitate the implantation of above described implant components as well as cases and trays to hold these instruments during sterilization and their subsequent storage.

Intended Use and Indications for Use:

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.
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Summary of Technological Characteristics:

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

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

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  Stem Extensions
  - Stem housing cantilever fatigue per internal test method
  - Four-point bending fatigue strength per internal test method

  Instrumentation
  - Functional relationship analyses (tolerance stack up)
  - Drill debris analysis per internal test method
  - Reliability verification per internal test method
  - Cadaveric design validation

  Cases and Trays
  - Distribution and handling verification per ASTM D4169

  System
  - 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.