October 25, 2018

Zimmer Inc.
Nicole Meredith
Regulatory Project Manager
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K181947
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: September 26, 2018
Received: September 27, 2018

Dear Ms. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Peter G. Allen -S
2018.10.25 18:22:34 -04'00'

FOR Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K181947

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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

Contact Person:

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

Date:

July 18, 2018

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:

Zimmer Persona	K133737
The Personalized Knee System	K130143
	K123459
	K122765
	K121771
	K113369
NexGen Complete Knee Solution	K173057
	K152494

	K960279 K946150 K933785
NexGen TM Augments and Cones	K103517 K040630 K031962 K024161
Vanguard SSK 360 Revision Knee System	K171054 K121149 K093293 K042757
Natural-Knee II	K173057 K023528 K013031 K982903 K973412 K972501

Purpose and Device Description: The purpose of this submission is for introduction of the Persona Revision Knee System.

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.

In addition, this submission includes the addition of MR conditional labeling for the Persona 14 x 30mm Tapered

Stem Extension cleared under the K133737 on February 2, 2014.

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.
- Moderate valgus, varus, or flexion deformities.
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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.

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:**
  Femoral Components
  - Patellofemoral durability per internal test method
  - Patellofemoral lateral constraint per ASTM F1672
  - Patellofemoral contact area and contact pressure per ASTM F1672
  - Posterior condyle fatigue per engineering analysis

- Intercondylar notch and anterior chamfer strength per engineering analysis
- Anterior flange strength via finite element analysis
- Stem housing cantilever fatigue per internal test method

Articular Surfaces

- Wear per ISO 14243-1
- Anterior spine impingement via finite element analysis
- Constraint per ASTM F2083 and ASTM F1223
- Contact area and contact pressure per ASTM F2083
- Anterior lift-off per engineering analysis
- Posterior lift-off per engineering analysis
- Combined internal/external (I/E) and varus/valgus (V/V) spine loading via finite element analysis
- Static varus/valgus constraint per internal test method
- Assembly/insertion force per internal test method
- Secondary lockdown screw assembly strength per internal test method
- Secondary lockdown screw torque after gait-type loading per internal test method

Tibial Components

- Cantilever fatigue per ASTM F1800
- Tibial stem housing cantilever fatigue per internal test method
- Locking mechanism static shear strength per engineering analysis
- Fixation stability per internal test method

Augments

- Shear attachment strength per internal test method
- Attachment screw assembly strength per internal test method

Cones

- Tibial cone stress under physiologic loading per finite element analysis
- Femoral cone stress under physiologic loading per finite element analysis

Stem Extensions

- Tibial taper connection axial pull-off and torsional strength per ASTM F2009
- Femoral taper connection axial pull-off and torsional strength per ASTM F2009
- Splined stem tip fatigue strength per internal test method
- Cantilever fatigue via finite element analysis per ASTM F1800

System

- Fretting/corrosion of modular junctions per engineering analysis
- MR compatibility per engineering analysis
- Testing to establish product non-pyrogenicity

Backwards Compatibility with Persona Primary Knee System

- Persona Revision femoral components wear on Persona Primary PS and CPS articular surfaces per engineering analysis
- Persona Revision femoral components posterior crush loading of the Persona Primary PS and CPS articular surfaces per finite element analysis
- Persona Revision femoral components anterior lift-off of the Persona Primary PS and CPS articular surfaces per engineering analysis
- Persona Revision femoral components posterior lift-off of the Persona Primary PS and CPS articular surfaces per engineering analysis
- Contact area and contact pressure of the Persona Revision femoral components with the Persona Primary PS and CPS articular surfaces per engineering analysis
- Tibiofemoral constraint of the Persona Revision femoral components with the Persona Primary PS and CPS articular surfaces per engineering analysis
- Persona Revision femoral components anterior spine impingement with the Persona Primary PS and CPS articular surfaces per engineering analysis
- Cantilever fatigue of the Persona Revision tibial components with the Persona Primary PS and CPS articular surfaces and Persona Primary tibial

components with Persona Revision articular surfaces per engineering analysis

- **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.