March 18, 2021

Zimmer, Inc.
Romil Sheth
Regulatory Affairs Project Manager
1800 W. Center Street
Warsaw, Indiana 46580

Re: K210551
Trade/Device Name: Persona Revision 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 23, 2021
Received: February 25, 2021

Dear Romil Sheth:

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, Ph.D., R.A.C.
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)*
Not Known
K210551

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 confi guration, 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

Sponsor:

Zimmer, Inc.
1800 W. Center Street
Warsaw, IN 46580
Establishment Registration Number: 1822565

Contact Person:

Romil Sheth
Regulatory Affairs Project Manager
Telephone: (574-268-8196)
Romil.Sheth@zimmerbiomet.com

Date:

March 16, 2021

Subject Device:

Trade Name: Persona® Revision Knee System
Common Name: Knee Prosthesis
Classification Name:

- JWH – Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer (21 CFR 888.3560 – Knee joint Patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis)
- MBH – Prosthesis, Knee, Patello/Femorotibial, Semi-Constrained, Uncemented, Porous, Coated, Polymer/Metal/Polymer (21 CFR 888.3565 – Knee joint Patellofemorotibial metal/polymer porous-coated uncemented prosthesis)
- OIY – Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer + Additive/Metal/Polymer + Additive (21 CFR 888.3560 – Knee joint Patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis)

Predicate Device(s):

K191625	*Persona* Revision Knee System	Zimmer, Inc.

Device Description:

The purpose of this submission is to obtain clearance for the proposed changes to the contraindications for the *Persona* Revision Knee System. The proposed contraindications changes are to align the use of *Persona* Revision Knee System with the current standard practice of revision knee prostheses and for clarification purpose.

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.

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.

- 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.

Summary of Technological Characteristics:

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

- **Intended Use:** Same as the predicate device.
- **Indications for Use:** Same as the predicate device.
- **Materials:** Same as the predicate device.
- **Design Features:** Same as the predicate device.
- **Sterilization:** Same as the predicate device.

Summary of Performance Data (Nonclinical and/or Clinical)

Non-clinical or clinical tests are not needed to support the proposed changes to contraindications.

Substantial Equivalence Conclusion

Based on the information contained within this submission, it is concluded that the *Persona* Revision Knee System is substantially equivalent to the identified predicate device.