October 17, 2022

Lauren Ricker
Regulatory Affairs Project Manager
1800 W Center Street
Warsaw, Indiana 46581-0708

Re: K222566
Trade/Device Name: Zimmer Persona Personalized 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: August 23, 2022
Received: August 24, 2022

Dear Lauren Ricker:

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.
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)*

K222566

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 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.**

**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 Zimmer 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 September 13, 2019.

**Sponsor:**

Zimmer, Inc.
1800 W. Center Street
Warsaw, IN 46581-0708
Establishment Registration Number: 1822565

**Contact Person**:

Lauren Ricker
Regulatory Affairs Project Manager
Telephone: 574-306-7578

**Date:**

August 23, 2022

**Subject Device:**

**Zimmer Persona Vivacit-E Polyethylene Shelf Life Extension**

**Classification Name:**

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

**Predicate Device(s):**

| | | |
|---|---|---|
| K121771 | Zimmer Persona Personalized Knee System | Zimmer Inc |
| K123459 | Zimmer Persona Personalized Knee System | Zimmer Inc |
| K150090 | Zimmer Persona Personalized Knee System | Zimmer Inc |

| | | |
|---|---|---|
| K172524 | Zimmer Persona Personalized Knee System | Zimmer Inc |

**Purpose and Device Description:**

Zimmer Inc Persona Personalized Knee System offers Vivacit-E polyethylene components that are sterile packaged with a shelf life of 5 years. The purpose of this submission is to extend the shelf life of these polyethylene components by re-packaging and re-sterilizing unexpired product and product expired up to 3 months post-expiration date. The rework of these devices to extend the shelf life by an additional 5 years does not change the intended use or fundamental scientific technology of the device.

**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:** Same as the predicate devices
- **Indications for Use:** Same as the predicate devices
- **Materials:** Same as the predicate devices
- **Design Features:** Same as the predicate devices
- **Sterilization:** Sterilization methods remain the same. However, sterile packaged devices unexpired or up to 3 months post-expiration may be re-cleaned, re-sterilized and re-packaged to extend the shelf life of the device by an additional 5 years.

**Summary of Performance Data (Nonclinical and/or Clinical):**

**Non-Clinical Tests:**

The following testing/evaluations were performed for the subject devices and are included in this 510(k) submission:

- Shelf Life Extension of Vitamin E Highly Crosslinked Polyethylene (Vivacit-E) After Ethylene Oxide Re-sterilization
- Biological Safety Assessment of Ethylene Oxide Re-sterilized Vivacit-E Device Components After Shelf-Life Extension

**Substantial Equivalence Conclusion:**

The intended use, indications for use, materials, design features and sterilization methods of the subject devices are the same as that of the predicate devices. The testing/evaluation and the biological safety assessment included in this 510(k) submission demonstrates that the subject polyethylene devices are substantially equivalent to the predicate devices and remain safe and effective.