April 26, 2024

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

Re: K240299
Trade/Device Name: Persona the Personalized Knee System (Persona OsseoTi 3-Peg Patella)
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: April 5, 2024
Received: April 5, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2024.04.26 13:16:43 -04'00'

For Lixin Liu, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240299

Device Name

Persona the Personalized Knee System (Persona OsseoTi 3-Peg Patella)

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 Personalized 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 Personalized Alignment (PA) surgical technique may only be used with Persona cemented and uncemented CR femoral components, Persona CR, Ultra Congruent (UC), and Medial Congruent (MC) articular surface components, the Persona Cemented Stemmed tibial components without a stem extension, and the Persona OsseoTi Keel Tibia and Cemented Keel Tibia.

Porous coated components may be used cemented or uncemented (biological fixation), except for the Persona OsseoTi Keel Tibia and the Persona OsseoTi 3-peg Patella which are for uncemented use only. 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) #: K240299

510(k) Summary

Prepared on: 2024-04-05

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Zimmer, Inc.
Applicant Address	1800 W. Center Street Warsaw IN 46580 United States
Applicant Contact Telephone	(574) 371-0519
Applicant Contact	Dr. Gregory Foster
Applicant Contact Email	gregory.foster@zimmerbiomet.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Persona the Personalized Knee System (Persona OsseoTi 3-Peg Patella)
Common Name	joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Classification Name	Prosthesis, Knee, Patello/Femorotibial, Semi-Constrained, Uncemented, Porous, Coated, Polymer/Metal/Polymer
Regulation Number	888.3565
Product Code(s)	MBH, JWH, OIY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K031462	Nexgen Primary Porous Patella	MBH
K073286	Gender Solutions Natural-Knee Flex System: Natural Knee Flex I	JWH
K221479	Persona OsseoTi™ 0° Porous Keel Tibia Baseplates	JWH

Device Description Summary

21 CFR 807.92(a)(4)

The purpose of this submission is to add a new component to the Persona Personalized Knee System. The component is the Persona OsseoTi 3-Peg Patella and the associated instruments. The addition of these components do not change the intended use or fundamental scientific technology of the device system.

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 a new porous metal backed UHMWPE patella component will be added to the system. These patellar components articulate against femoral component as part of a total knee system. The new patellar components come in a variety of sizes to match the needs of a patient's anatomy when performing total knee arthroplasty. These components are provided sterile and single use. To aid the implantation of these devices several new reusable instruments are also introduced.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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 Personalized 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 Personalized Alignment (PA) surgical technique may only be used with Persona cemented and uncemented CR femoral components, Persona CR, Ultra Congruent (UC), and Medial Congruent (MC) articular surface components, the Persona Cemented Stemmed tibial components without a stem extension, and the Persona OsseoTi Keel Tibia and Cemented Keel Tibia.

Porous coated components may be used cemented or uncemented (biological fixation), except for the Persona OsseoTi Keel Tibia and the Persona OsseoTi 3-peg Patella which are for uncemented use only. All other femoral, tibial baseplate and all-polyethylene (UHMWPE and VEHXPE) patella components are indicated for cemented use only.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications are similar between the predicate and the subject device, with the exception that the predicate is for cemented and uncemented use, and the subject device is for uncemented use only.

Technological Comparison 21 CFR 807.92(a)(6)

The subject and predicate devices are both metal-backed porous patellar resurfacing prostheses, with a direct compression molded UHMWPE articulating surface. The articulating geometry are equivalent between the predicate and the subject devices. The difference is that the predicate has a Trabecular Metal(TM) porous bone-contacting surface and a single peg, while the subject device has an OsseoTi (TM) additive manufactured porous surface and a 3 peg configuration.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Shear and Torsional Strength of the Persona Link OsseoTi Patella Polyethylene -Ti6Al4V Interface

Fatigue Strength of the Persona OsseoTi Porous Patella in an Undersupported Bending Configuration and Manufactured Using PQ Process Parameters
Shear Fatigue Strength of Persona OsseoTi Porous Patella Pegs Manufactured Using PQ Process Parameters

Durability Testing, per ISO 14243-5, for the Persona OsseoTi 3- Peg Patella when Articulated with a Persona CR Femoral Component

Expanded In Vivo RF-Induced Heating Simulations for the Persona Primary Knee System

Characterization of As-Printed Four-Point Bend Fatigue Strength

Evaluation of the Interfacial Motion Between the Persona OsseoTi Patella and a Bone Analog When Subjected to Physiologically Derived Patellofemoral Joint Kinetics and Kinematics

Characterization of OsseoTi Lattice

Clinical Testing Not Applicable

The proposed device has the same intended use as the predicate(s). The proposed device has similar technological characteristics to the predicate(s), and the information provided herein demonstrates 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 device(s).