DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 22, 2014

Zimmer, Incorporated
Mr. Dan Williman
Project Manager, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581

Re: K142787
Trade/Device Name: Zimmer® Persona® Personalized 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: September 25, 2014
Received: September 26, 2014

Dear Mr. Williman:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142787

Device Name
Zimmer® Persona® Personalized 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 coated components may be used cemented or uncemented (biological fixation). All other femoral, tibial baseplate, and all-polyethylene (UHMWPE and VEXLPE) 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

510(k) Summary

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Daniel J. Williman Project Manager, Regulatory Affairs Telephone: 574-371-8065 Fax: 574-372-4605
Date:	September 25, 2014
Trade Name:	*Zimmer*® *Persona*® The Personalized Knee System
Product Codes / Device:	MBH, OIY, JWH
Regulation / Description:	21 CFR § 888.3565 – Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis 21 CFR § 888.3560 – Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Classification Panel:	Orthopedics/87
Predicate Device(s):	*Persona*™ Personalized Knee System (K113369, cleared March 27, 2012) *NexGen* Complete Knee Solution Legacy Posterior Stabilized (LPS)-Flex Fixed Bearing Tivanium Ti-6Al-4V Alloy Femoral Components, manufactured by Zimmer, Inc. (K062768, cleared October 13, 2006) Legion Primary Knee System, manufactured by Smith & Nephew, Inc., (K093746, cleared April 14, 2010)
Purpose and Device Description:	The *Persona* Personalized Knee System is a semi-constrained modular knee prosthesis designed to resurface the articulating surface of the femoral, tibial and patellar bones. With this submission, femoral components made

from Titanium alloy (ASTM F136-13) with a Titanium Nitride surface treatment are being added to the system (5050, 5056, 5070, 5076 femoral component families). These femoral components articulate against tibial and patellar articular surfaces to form a total knee system. They are available in Cruciate Retaining (CR) and Posterior Stabilized (PS) designs. Both designs are available in multiple sizing options to accommodate a wide range of anatomies. "Narrow" femoral components have a smaller M/L dimension than the "Standard" femoral components. The PS and CR femoral components, when used with a PS or CR articular surface component, can accommodate a maximum active flexion of 155°. The CR femoral component, when used with an Ultra-Congruent (UC) articular surface, can accommodate a maximum active flexion of 145°. The PS femoral component, when used with a Constrained Posterior Stabilized (CPS) articular surface, can accommodate a maximum active flexion of 135°. These femoral components are provided sterile and single use to the healthcare facility/hospital.

Intended 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 coated components may be used cemented or uncemented (biological fixation). All other femoral, tibial baseplate, and all-polyethylene (UHMWPE and VEXLPE) patella components are indicated for cemented use only.

Comparison to Predicate Device: The proposed *Persona* Personalized Knee System femoral components are similar or identical in intended use, materials, sterility, and performance characteristics to the predicate devices. Testing described below was completed to demonstrate equivalence to the predicate devices.

Performance Data (Nonclinical and/or Clinical): Clinical Performance and Conclusions:

Clinical Data and conclusions were not needed for this device.

Non-Clinical Performance and Conclusions:

Performance testing and analyses were conducted on the proposed device per FDA's *Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses* and *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment*, as well as the standards identified in the test descriptions below.

Test	Results
Biocompatibility testing of Ti-6Al-4V alloy with bonded Titanium Nitride.	This test demonstrated that the material utilized by the subject femoral components meet ISO 10993-1 requirements. Therefore, there are no biocompatibility concerns.
Wear testing of the subject femoral components with Persona articular surfaces.	This test, completed per ISO 14243-3, demonstrated that the wear characteristics of the subject femoral components with Persona articular surfaces are equivalent to the predicate device Persona system.
Evaluation of Interactions with the Magnetic Fields in the Magnetic Resonance Imaging (MRI) Environment	This analysis demonstrated safety and compatibility of the Persona knee system within the MRI environment. Therefore, the Persona system can be used under the same MRI conditions previously defined for the predicate device system.