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Warsaw, IN 46581-0708
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zimmer

Summary of Safety and Effectiveness

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:	January 25, 2013
Trade Name:	*Zimmer® Persona*™ Personalized Knee System
Product Codes / Device:	MBH, OIY, JWH
Regulation Numbers / 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
Predicate Device:	*Persona*™ Personalized Knee System (K113369, cleared March 27, 2012) *Zimmer® Persona*™ The *Personal*ized Knee System (K121771, cleared November 7, 2012) *NexGen* Complete Knee Solution Legacy Posterior Stabilized (PS) and Constrained Condylar Knee (LCCK), manufactured by Zimmer, Inc. (K960279 cleared April 26, 1996) *NexGen* Complete Knee Solution LPS-Flex *Prolong* Highly Crosslinked Polyethylene Articular Surfaces, manufactured by Zimmer, Inc. (K042271, cleared October 13, 2004)

Device Description:

The *Zimmer Persona* Personalized Knee System is a semi-constrained modular knee prosthesis designed to resurface the articulating surface of the femoral, tibial and patellar bones. The *Persona* Knee System utilizes a modular design between the tibial plates and articular surfaces. The addition of the Constrained Posterior Stabilized (CPS) *Vivacit-E®* articular surface components will provide surgeons with the ability to obtain moderate varus/valgus and/or internal/external rotation constraint compared to the existing *Persona* PS articular surfaces. CPS articular surfaces are for use with cemented nonporous tibial and femoral components only.

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 *Zimmer Persona* Personalized Knee System components are similar or identical in intended use, materials, sterility, and performance characteristics 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:

Vivacit-E material characteristics for the CPS articular surfaces are identical to the material characteristics of the currently marketed Zimmer *Vivacit-E* Polyethylene Liners (K120370) and *Persona Vivacit-E* articular surfaces (K121771). In contrast to conventional polyethylene, the *Vivacit-E* material is delamination resistant and exhibits a reduction in wear according to knee simulator bench testing.

Bench testing outlined below was conducted in support of this device:

Property or Characteristics	Test Results
Anterior Tibiofemoral Constraint Evaluation of the *Persona* CPS *Vivacit-E* UHMWPE Articular Surfaces with the Lowest Anterior Jump Height	Demonstrated that the *Persona* CPS *Vivacit-E* articular surfaces provide adequate anterior subluxation constraint through the necessary tibiofemoral flexion movements.
Anterior and Posterior Liftoff Testing of the *Persona* CPS *Vivacit-E* UHMWPE Articular Surfaces	Demonstrated sufficient locking mechanism strength to survive potential worst case anterior and posterior liftoff loading conditions, respectively.
Evaluation of Interactions of the Zimmer *Persona* Primary and *Persona* Porous Knee Implant Systems with the Magnetic Fields in the Magnetic Resonance Imaging (MRI) Environment	Demonstrated safety and compatibility of the *Persona* knee system within the MRI environment.
Spine Fatigue and Underspine Fatigue Evaluation of the *Persona* CPS *Vivacit-E* UHMWPE Articular Surfaces	Demonstrated sufficient resistance to spine fracture, underspine fracture, and locking mechanism dissociation during worst case walking gait conditions.
Spine Fatigue Evaluation of the *Persona* CPS *Vivacit-E* Articular Surfaces	Demonstrated that the spine of the *Persona Vivacit-E* CPS articular surfaces has sufficient strength to survive expected in-vivo loading conditions.
Spine Fracture and Locking Mechanism Resistance of *Persona* CPS *Vivacit-E* UHMWPE During Varus/Valgus Loading	Demonstrated sufficient locking mechanism and articular surface spine strength to withstand worst case varus or valgus loading conditions.
Tibiofemoral Constraint Evaluation of the *Persona* CPS *Vivacit-E* UHMWPE	Determined the anterior-posterior, medial-lateral, internal-external and varus-valgus constraint of the *Persona* CPS *Vivacit-E* articular surfaces through the necessary tibiofemoral flexion movements.

Property or Characteristics	Test Results
Tibiofemoral Contact Area and Contact Pressure Evaluation of the *Persona* CPS *Vivacit-E* UHMWPE Articular Surfaces	Determined the contact area and contact pressure of the *Persona* CPS *Vivacit-E* articular surfaces through the necessary tibiofemoral flexion movements.
Wear Testing of *Persona* CPS *Vivacit-E* UHMWPE Articular Surfaces	Demonstrated that the wear characteristics of the *Persona* CPS *Vivacit-E* articular surfaces, when articulated against the *Persona* PS femoral component, are sufficient to survive expected in vivo loading conditions.
EO Residual Testing of *Persona* CPS *Vivacit-E* UHMWPE Articular Surfaces	Demonstrated acceptable residual levels following EO sterilization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 22, 2013

Zimmer, Incorporated
% Mr. Daniel Williman
Project Manager, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K123459
Trade/Device Name: Zimmer® Persona™ 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: January 25, 2013
Received: January 28, 2013

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Erin L. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123459

Device Name:

Zimmer® Persona™ Personalized Knee System

Indications for Use:

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- Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
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Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

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