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

DEC 0 5 2012

Summary of Safety and Effectiveness

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Pauline A. Shand Sr. Specialist, Regulatory Affairs Telephone: (574) 372-4765 Fax: (574) 372-4605
Date:	September 20, 2012
Trade Name:	*Zimmer® Persona*™ Personalized Knee System
Product Codes / Device:	MBH, JWH, OIY
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
Predicate Device:	*Persona*™ Personalized Knee System (K113369, cleared March 27, 2012) *NexGen® Trabecular Metal*™ Metal Tibial Tray (K072160, cleared September 5, 2007) *NexGen®* Complete Knee Solution Cruciate Retaining Flex Femoral (CR Flex) Components, manufactured by Zimmer, Inc. (K023211, cleared October 17, 2002)

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NexGen® LPS-Flex Porous Femoral Component, NexGen Gender Solutions Female (GSF), CR-Flex and LPS-Flex Porous Femoral components, manufactured by Zimmer, Inc. (K072619, cleared November 21, 2007

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. The *Persona* Knee System utilizes a modular design between the tibial plates and articular surfaces. The addition of the *Trabecular Metal*™ femoral component will provide surgeons with the ability to implant with, or without cement (biological fixation).

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.

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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:

Bench testing outlined below was conducted according to FDA guidance documents:

FDA Guidance: Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses

FDA Guidance: Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement

FDA Guidance: Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment

Property or Characteristic	Test Results
Posterior Condyle Fatigue Testing in a Cantilever Loading Condition of the *Persona™ Tracebular Metal™* femoral component	Demonstrated adequate posterior condyle fatigue strength of the uncemented *Persona™ Trabecular Metal™* femoral component in the cantilever loading condition
Posterior Condyle Fatigue of *Persona™ Tracebular Metal™* femoral component in three-point Bend Loading Condition	Demonstrated adequate posterior condyle fatigue performance of the *Persona™ Tracebular Metal™* femoral component in a 3-point bend loading condition
Modified Metallic Surface Characterization for the *Persona™ Tracebular Metal™* Porous femoral knee component with *Trabecular Metal™*.	Mechanical, physical, and chemical analyses of *Trabecular Metal™* were assessed in accordance to the Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement

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Static Tensile, Static Shear and Shear Fatigue of *Trabecular Metal*™ Diffusion Bonded to Zimaloy-One Hour Cycles, 0.28mm Ti Sheet Interlayer	Demonstrated that one hour diffusion bonding cycles for *Trabecular Metal*™ produces a bond that met the 20 MPa static tensile test and static shear acceptance criteria.
Evaluation of Interactions of the Zimmer Legacy Knee and Persona Primary Implant Systems with the Magnetic Fields in the Magnetic Resonance Imaging (MRI) Environment	Demonstrated safety and compatibility within the MRI environment.

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

Zimmer, Incorporated
% Ms. Pauline A. Shand
Senior Specialist, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Letter dated: December 5, 2012

Re: K122745
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: II
Product Codes: MBH, JWH, OIY
Dated: September 6, 2012
Received: September 7, 2012
Amended: September 24, 2012

Dear Ms. Shand:

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,

Mark N. Melkerson

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): K122745

Device Name:

Zimmer® Persona™ Personalized Knee System

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This device is indicated for patients with severe knee pain and disability due to:

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Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (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)

Krishna Asundi
for (Division Sign-Off)
Division of Orthopedic Devices

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