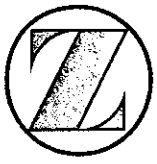

K113369

MAR 27 2012

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

## Summary of Safety and Effectiveness

| | |
|---|---|
| **Sponsor:** | Zimmer, Inc.<br>P.O. Box 708<br>Warsaw, IN 46581-0708 |
| **Contact Person:** | Kelli Anderson<br>Project Manager, Regulatory Affairs<br>Telephone: (574) 371-8087<br>Fax: (574) 372-4605 |
| **Date:** | March 16, 2012 |
| **Trade Name:** | *Zimmer® Persona*™ Personalized Knee System |
| **Product Codes / Device:** | JWH |
| **Regulation Numbers / Description:** | 21 CFR § 888.3560 - Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented |
| **Predicate Device:** | *Natural Knee* II System, manufactured by Zimmer, Inc. (K936159, cleared May 22, 1995)<br><br>*Gender Solutions*™ *Natural Knee*® Flex System, manufactured by Zimmer, Inc. (K070214, cleared March 16, 2007 and K073286, cleared March 7, 2008)<br><br>*NextGen* Complete Knee System, manufactured by Zimmer, Inc. (K933785, cleared January 30, 1995)<br><br>*NexGen* Complete Knee Solution Legacy Posterior Stabilized (PS) and Constrained Condylar Knee (CCK), manufactured by Zimmer, Inc. (K960279, cleared April 26, 1996)<br><br>*NexGen*® Complete Knee Solution *Legacy*® Posterior Stabilized (LPS); LPS-Flex Fixed Bearing Femoral and Articular Surface Components, manufactured by Zimmer, Inc. (K991581, cleared July 30, 1999) |

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*NexGen*® Complete Knee Solution Cruciate Retaining Flex Femoral (CR Flex) Components, manufactured by Zimmer, Inc. (K023211, cleared October 17, 2002)

*NexGen*® Knee Gender Solutions Female (GSF) Femoral Components, manufactured by Zimmer, Inc. (K060370, cleared April 28, 2006)

**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.

**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.

This device is intended 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:

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| Property or Characteristic | Test Results |
|---|---|
| **Fatigue Test of the *Persona* Tibia Keel and Stem Extension** | Demonstrated that the *Persona* tibia keel and stem extension taper junction provide sufficient fatigue strength to survive expected worst case loading conditions. |
| **Cantilever Fatigue Test of the *Persona* Cemented Tibia** | Demonstrated adequate fatigue strength in the cantilever loading condition. |
| **Wear Testing of *Persona* CR Conventional Articular Surfaces Under Load and Motion Curves From the ISO 14243 Standard** | Demonstrated that the wear characteristics of the *Persona* CR articular surfaces, when articulated against the *Persona* CR femoral component, are sufficient to survive expected *in vivo* loading conditions. |
| **Wear Testing of *Persona* PS Conventional UHMWPE Articular Surfaces Under Load and Motion Curves from the ISO 14243 Standard** | Demonstrated that the wear characteristics of the *Persona* PS articular surfaces, when articulated against the *Persona* PS femoral component, are sufficient to survive expected *in vivo* loading conditions. |
| **Wear Testing of *Persona* UC Conventional UHMWPE Articular Surfaces Under Displacement Control with Load and Motion Curves from the ISO 14243-1 Standard** | Demonstrated that the wear characteristics of the *Persona* UC articular surfaces, when articulated against the *Persona* CR femoral component, are sufficient to survive expected *in vivo* loading conditions. |
| **Spine Fatigue Evaluation of the *Persona* PS Conventional UHMWPE Articular Surfaces** | Demonstrated that the spine of the *Persona* PS articular surfaces has sufficient strength to survive expected *in vivo* stress/strain loading conditions. |
| **Tibiofemoral Constraint Evaluation of the *Persona* Conventional UHMWPE Articular Surface** | Demonstrated that constraint values for the *Persona* articular surfaces are comparable to data from similar *NexGen* articular surfaces. Therefore, the *Persona* articular surfaces provide adequate constraint through the needed tibiofemoral flexion angles. |

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| Property or Characteristic | Test Results |
|---|---|
| **Lateral Constraint Evaluation of the *Persona* Conventional All-Poly Patellar Component on the *Persona* CR and PS Femoral Components** | Demonstrated that the lateral subluxation force of the *Persona* conventional all-poly patellar component on the *Persona* CR and PS femoral implants at tibiofemoral flexion angles 0° to 90° was comparable to control testing on *NexGen* predicate devcies. |
| **Tibiofemoral Contact Area and Contact Pressure Evaluation of the *Persona* CR/UC/PS Conventional Articular Surfaces** | Demonstrated that the contact area and contact pressure of the *Persona* articular surfaces are comparable to data from previous testing on similar *NexGen* articular surfaces. |
| **Contact Area and Contact Stress Evaluation of the *Persona* Conventional All-Poly Patellar Component on the Persona Primary CR and PS Femoral Components** | Demonstrated that, for all flexion angles, the contact areas were similar between the CR and PS femoral components. |
| **Anterior Liftoff Testing of the *Persona* Articular Surfaces** | Demonstrated sufficient locking mechanism strength to survive potential worst case anterior liftoff loading conditions during deep flexion. |
| **Posterior Liftoff Fatigue Strength of the *Persona* Articular Surfaces** | Demonstrated sufficient locking mechanism strength to survive potential worst case shear loading conditions. |
| **Assembly Testing of the *Persona* Tibia Locking Mechanism** | Demonstrated successful assembly of the modular articular surfaces at normal and maximum interference conditions. |
| **Static Shear Strength of the *Persona* Tibia Locking Mechanism** | Demonstrated adequate resistance of the modular articular surfaces to disassembly.. |

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Zimmer, Inc.
% Ms. Kelli J. Anderson
Project Manager, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

MAR 2 7 2012

Re: K113369
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: II
Product Codes: JWH
Dated: March 16, 2012
Received: March 19, 2012

Dear Ms. Anderson:

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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

**510(k) Number (if known):** ~~Unknown~~ K113369

**Device Name:**

Persona™ Knee System

**Indications for 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.

This device is intended for cemented use only.

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)

(Division Sign-Off)
**Division of Surgical, Orthopedic, and Restorative Devices**

**510(k) Number** K113369