

FEB - 4 2014



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Warsaw, IN 46581-0708
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Summary of Safety and Effectiveness

Sponsor: Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

Contact Person: Pauline A. Shand
Associate Project Manager, Regulatory Affairs
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Date: January 24, 2014

Trade Name: Zimmer® *Persona* The Personalized Knee System
14 x+30mm Tapered Stem Extension

Product Codes / Device: JWH, OIY

Regulation Numbers / Description: 21 CFR § 888.3560 - Knee joint patellofemorotibial
polymer/metal/polymer semi-constrained cemented

Predicate Device: *Persona* Personalized Knee System (K113369, cleared
March 27, 2012)

M-G II® Total Knee System Stemmed Tibial Baseplate
Components (K050723, cleared April 20, 2005)

NexGen® Complete Knee Solution (K933785, cleared
January 30, 1995)

Device Description: The *Persona* 14 x+30mm Tapered Stem Extension is
intended for implantation for total knee arthroplasty (TKA)
when supplemental tibial baseplate support is needed.
Extending into the intramedullary canal from the base of

the *Persona* Cemented Stemmed Tibia Baseplate, the *Persona* 14 x+30mm Stem Extension provides supplemental support and shields the fixation interfaces from excessive stress by resisting bending and torsional moments. The subject device is intended to be used with cement knee constructs.

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 to be used with cemented knee constructs.

Comparison to Predicate Device:

The proposed Zimmer® *Persona* The Personalized Knee System 14 x+30mm Tapered Stem Extension is 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:

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 non-articulating, “mechanically locked”, modular implant components.

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

Property or Characteristic	Test Results
Fatigue Test of the <i>Persona</i> Tibia Keel and Stem Extension	Demonstrated that the <i>Persona</i> tibia keel and stem extension taper junction has sufficient fatigue strength to survive expected worst case loading conditions.
Static Axial and Torsional Strength of the <i>Persona</i> Stem Extension Taper	Demonstrated the static axial and torsional strength of the <i>Persona</i> stem extension taper mechanism.
The Risk of Cortex Perforation for <i>Persona</i> Tibial Components with +30MM Stem	Assessed the potential risk of cortex perforation of the <i>Persona</i> stemmed tibial implant with the 14 x +30mm stem extension compared to the <i>NexGen</i> tibial implant when implanted in the same manner.



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

February 4, 2014

Zimmer, Incorporated
% Ms. Pauline A. Shand
Associate Project Manager, Regulatory Affairs
Zimmer, Incorporated
P.O. Box 708
Warsaw, Indiana 46581

Re: K133737

Trade/Device Name: Zimmer® *Persona* The Personalized Knee System 14 x+30mm
Tapered Stem Extension
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, OIY
Dated: December 6, 2013
Received: December 9, 2013

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

Vincent J. Devlin -S

for
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): K133737

Device Name:

Zimmer® *Persona* The Personalized Knee System 14 x+30mm Tapered Stem Extension

Indications for Use:

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

- Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
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This device is intended to be used with cemented knee constructs.

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)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices