K113296

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

SEP 14 2012

Summary of Safety and Effectiveness

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Daniel J. Williman Associate Project Manager, Regulatory Affairs Telephone: 574-371-8065 Fax: (574) 372-4605
Date:	September 14, 2012
Trade Name:	*ZMR*® Hip System
Product Code / Device:	LZO - Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented LPH - Prosthesis, hip, semi-constrained, metal/polymer, porous uncemented LWJ - Prosthesis, hip, semi-constrained, metal/polymer, uncemented JDI – Prosthesis, hip, semi-constrained, metal/polymer, cemented KWZ - Prosthesis, hip, constrained, cemented or uncemented, metal/polymer
Regulation Number / Description:	21 CFR 888.3353 - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis 21 CFR 888.3358 - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

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21 CFR 888.3360 - Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis

21 CFR § 888.3350 – Hip joint metal polymer, semi-constrained cemented prosthesis

21 CFR § 888.3310 – Hip joint metal/polymer constrained, cemented or uncemented prosthesis

Predicate Device:

ZMR Hip System - Revision Taper, manufactured by Zimmer, Inc, K992667, cleared October 27, 1999

ZMR Hip System – Porous Revision, manufactured by Zimmer, Inc, K994286, cleared March 10, 2000

ZMR Hip System - XL, manufactured by Zimmer, Inc, K031572, cleared June 24, 2003

Taperloc Complete System and Taperloc Complete Microplasty System, manufactured by Biomet, Inc., K101086, cleared September 3, 2010 and K110400, cleared September 30, 2011

DJO Surgical Revision Femoral Hip System, manufactured by Encore Medical, L.P., K092331, cleared March 3, 2010

Trabecular Metal Acetabular Augments, manufactured by Zimmer Trabecular Metal Technology, K061067, cleared May 25, 2006 and K042871, cleared December 21, 2004

Hedrocel Acetabular Restrictor, manufactured by Implex Corp., K962468, cleared February 3, 1997

Zimmer *Trabecular Metal* Acetabular Revision System Cage, manufactured by Zimmer, Inc, K061226, cleared August 2, 2006.

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Device Description:

The *ZMR* Hip System is a modular hip system for cementless revision hip arthroplasty. The stem assembly is manufactured from *Tivanium*® Ti-6Al-4V Alloy and utilizes modular junctions between the head and neck, and the metaphyseal body and diaphyseal stem segments. A variety of body and stem components are provided to achieve fixation and restore joint kinematics. The femoral stem assembly contains a 12/14 taper designed to mate with the corresponding femoral head component.

The stems may be used for total hip and hemi-hip arthroplasty. During total hip arthroplasty, the stems may be combined with constrained or semi-constrained acetabular systems and acetabular augments, restrictors, and cages. Both the indications for use provided below and the indications for use provided with those devices combined with the *ZMR* Hip System must be followed.

Intended Use:

The *ZMR* Hip System is indicated for cementless revision hip arthroplasty. Arthroplasty should be performed only when more conservative methods of treatment have failed to provide symptomatic relief or when there is progressive disability.

Comparison to Predicate Device:

The *ZMR* Hip System is similar or identical in intended use, materials, sterility, and performance characteristics to the predicate device(s).

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

The results of non-clinical (lab) performance testing demonstrate that the devices are safe and effective and substantially equivalent to the predicate devices. Performance testing/analysis included Fretting Fatigue Testing and Range of Motion Analyses.

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Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

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

SEP 14 2012

Re: K113296
Trade/Device Name: ZMR® Hip System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.
Regulatory Class: Class II
Product Code: LPH, LZO, LWJ, JDI, KWZ
Dated: September 10, 2012
Received: September 12, 2012

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,

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

Enclosure

K113296

Indications for Use

510(k) Number (if known): K113296

Device Name:

ZMR® Hip System

Indications for Use:

The *ZMR* Hip System is indicated for cementless revision hip arthroplasty. Arthroplasty should be performed only when more conservative methods of treatment have failed to provide symptomatic relief or when there is progressive disability.

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

510(k) Number K113296

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)