K093561

p. 1/3

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

APR 28 2010

Summary of Safety and Effectiveness

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Benjamin C. Curson, RAC Associate Project Manager, Regulatory Affairs Telephone: (574) 372-4119 Fax: (574) 372-4605
Date:	April 26, 2010
Trade Name:	Zimmer *Trabecular Metal*™ Modular Acetabular System
Product Code / Device:	LPH – Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented. JDI – Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented LZO – Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented KWZ – Prosthesis, Hip, Constrained, Cemented or Uncemented, Metal/Polymer

K093561

p. 2/3

Regulation Number / Description:

21 CFR § 888.3358 – Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.

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

21 CFR § 888.3353 – Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

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

Predicate Device:

Zimmer *Trabecular Metal*™ Modular Acetabular System, manufactured by Zimmer, Inc. K021891, cleared September 05, 2002.

Trilogy® *Longevity*® Constrained Liner, manufactured by Zimmer, Inx. K071718, cleared July 13, 2007.

Device Description:

The Zimmer *Trabecular Metal* Modular Acetabular System is a modular acetabular cup system intended to replace a hip joint and designed to achieve biological fixation to bone without the use of bone cement; or, it may also be for cemented fixation. The system consists of a shell and polyethylene liner. The shell substrate is made from *Tivanium*™ Ti-6Al-4V Alloy. The outer porous material, which is metallurgically bonded to the shell substrate, is made of Trabecular Metal.

Three porous acetabular shell designs are available: one with multiple screw holes, one with cluster screw holes and one without screw holes. The shells range in diameter from 38 to 80mm in 2mm increments. The screw holes permit the use of *Tivanium* Ti-6Al-4V Alloy screws for immediate fixation and security. The shell incorporates a threaded polar hole to attach the cup positioner.

Intended Use:	The *Trabecular Metal* Modular Acetabular System with a *Trilogy* Neutral, Elevated, Offset or Oblique Liner is indicated for primary or revision surgery for rehabilitating hips damaged as a result of Noninflammatory degenerative joint disease (NIDJD) or its composite diagnoses of osteoarthritis, avascular necrosis, protrusio acetabuli, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis and diastrophic variant. The Trabecular Metal Modular Acetabular System with a *Trilogy Longevity*® Constrained Liner is indicated for primary or revision total hip arthroplasties where there is a high risk of hip dislocation due to a history of instability, bone loss, joint, muscle or tissue laxity, or disease condition. This device is intended for patients for whom all other options to constrained components have been considered. This device is intended for either cemented or noncemented use.
Comparison to Predicate Device:	The Zimmer *Trabecular Metal* Modular Acetabular System incorporates the same patient contact materials, has the same intended use, and similar technological and geometric features as the legally marketed predicate devices.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: Non-clinical testing was provided, including the information outlined in the FDA" Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement, 4/28/94;" and, an evaluation of the device design and geometry that demonstrated that the Zimmer *Trabecular Metal* Modular Acetabular System met performance requirements and is as safe and effective as its predicate and this information and testing data formed the basis for a determination of substantial equivalence.

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

APR 2 8 2010

Zimmer, Inc.
% Mr. Benjamin C. Curson, RAC
Associate Project Manager, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K093561
Trade/Device Name: Zimmer Trabecular Metal Modular Acetabular 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, JDI, LZO, KWZ
Dated: April 26, 2010
Received: April 27, 2010

Dear Mr. Curson:

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

K093561

Indications for Use

510(k) Number (if known):

Device Name:

Zimmer *Trabecular Metal*™ Modular Acetabular System

Indications for Use:

The *Trabecular Metal* Modular Acetabular System when used with a *Trilogy*® Neutral, Elevated, Offset or Oblique Liner is indicated for primary or revision surgery for rehabilitating hips damaged as a result of noninflammatory degenerative joint disease (NIDJD) or its composite diagnoses of osteoarthritis, avascular necrosis, protrusio acetabuli, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

The *Trabecular Metal* Modular Acetabular System when used with a *Trilogy Longevity*® Constrained Liner is indicated for primary or revision total hip arthorplasties where there is a high risk of hip dislocation due to a history of instability, bone loss, joint, muscle or tissue laxity, or disease condition. This device is intended for patients for whom all other options to constrained acetabular components have been considered.

This device is intended for either cemented or noncemented use.

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)

Janette D. for MXR

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

510(k) Number K093561