SEP 11 2009

K091508

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

zimmer

Summary of Safety and Effectiveness

Sponsor:

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

Contact Person:

Benjamin Curson, CQE RAC
Associate Project Manager, Regulatory Affairs
Telephone: (574) 372-4119
Fax: (574) 372-4605

Date:

May 21, 2009

Trade Name:

Continuum™ and *Trilogy*® Integrated Taper (IT) Acetabular Systems

Common Name:

Total Hip Prosthesis

Classification Name and Reference:

LPH - Prosthesis, Hip, Semi-constrained, metal/polymer, porous, uncemented; 21 CFR 888.3358

JDI - Prosthesis, Hip, Semi-constrained, metal/polymer, cemented; 21 CFR 888.3350

LZO - Prosthesis, Hip, Semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented; 21 CFR 888.3353

Predicate Device:

Trabecular Metal Acetabular System, manufactured by Zimmer, Inc. (K021891), *Trilogy* Acetabular System, manufactured by Zimmer, Inc. (K934765), Converge Acetabular System, manufactured by Zimmer, Inc. (K012739), Trilogy Acetabular System Large Head Liner, manufactured by Zimmer, Inc. (K002960), and Trilogy Acetabular System 46mm Large Head Liners, manufactured by Zimmer, Inc. (K003478)

K091508

Device Description:	The *Continuum* and *Trilogy* IT Acetabular Systems are modular acetabular cup systems intended to replace a hip joint and designed to achieve fixation to bone either with or without bone cement. The systems consist of porous coated shells, a polyethylene liner and optional screws. The shells with screw holes permit the use of *Tivanium* alloy screws to provide additional fixation and security, particularly in those cases where acetabular bone stock is deficient.
Intended Use:	The *Continuum* and *Trilogy* IT Acetabular Systems are 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 devices are intended for use either with or without bone cement.
Comparison to Predicate Device:	The *Continuum* and *Trilogy* IT Acetabular Systems are packaged, manufactured, and sterilized using the same materials and processes as their predicates. The subject device also has the same intended use and fixation methods as the predicate device.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: Non-Clinical testing demonstrated that the *Continuum* and *Trilogy* IT Acetabular Systems met performance requirements and are as safe and effective as their predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

SEP 11 2009

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

Re: K091508
Trade/Device Name: Continuum and Trilogy Integrated Taper Acetabular Systems
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH, LZO, JDI
Dated: August 11, 2009
Received: August 12, 2009

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.

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

K091508

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Traditional 510(k)
Premarket Notification

Indications for Use

510(k) Number (if known):

Device Name:

Continuum and *Trilogy* Integrated Taper (IT) Acetabular systems

Indications for Use:

The *Continuum* and *Trilogy* IT Acetabular Systems are 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 devices are intended for use either with or without bone cement.

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)

for MXR

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

510(k) Number K091508