K103662

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

A[illegible] 2011

Summary of Safety and Effectiveness

APR 15 2011

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Rebecca M. Brooks Specialist, Regulatory Affairs Telephone: (574) 371-8033 Fax: (574) 372-4605
Date:	February 10, 2011
Trade Name:	*Continuum*® and *Trilogy*® IT Acetabular Systems *Longevity*® IT Highly Crosslinked Polyethylene Elevated Liners *Longevity*® IT Highly Crosslinked Polyethylene Offset Liners *Longevity*® IT Highly Crosslinked Polyethylene Oblique Liners
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:	*Continuum*® and *Trilogy*® IT Acetabular Systems, manufactured by Zimmer, K091508, cleared 11 September 2009

K103662

	Continuum® and *Trilogy*® IT Acetabular Systems & *Longevity*® IT Highly Crosslinked Polyethylene Elevated Liners, manufactured by Zimmer, K101229, cleared 03 December 2010 *Trilogy*® Acetabular System *Longevity*® Liners, manufactured by Zimmer, K990135, cleared 12 July 1999
Device Description:	The proposed *Continuum* and *Trilogy* IT Acetabular System Shells are a line extension to the predicate modular acetabular shells, with a smaller 40 mm outer diameter. The *Longevity* IT Elevated Liner in this submission is offered in a size to be used with the 40 mm *Continuum* and *Trilogy* IT Shells above and has a 22 mm articulation diameter. The *Longevity* IT Offset and Oblique Liners are modular acetabular cup liners intended to be used with the *Continuum* and *Trilogy* IT Acetabular Systems. Offset Liners have a head center that is offset 7 mm beyond the acetabular shell center of rotation and the Oblique Liners have a liner face and head center tilted by 10° relative to the acetabular shell rim.
Intended Use:	The system is indicated for primary or revision surgery in skeletally mature individuals 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 system is intended for use either with or without bone cement in total hip arthroplasty.
Comparison to Predicate Device:	The *Continuum* and *Trilogy* IT Acetabular Shells and *Longevity* IT Highly Crosslinked Polyethylene Elevated, Offset, and Oblique Liners are manufactured, packaged, and sterilized using

K103662

equivalent materials and processes as their predicates. The subject devices also have the same intended use as their predicates.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Non-clinical testing demonstrated that the *Continuum* and *Trilogy* IT Acetabular Shells and the *Longevity* IT Elevated, Offset, and Oblique Liners met performance requirements.

The *Longevity* IT Elevated, Offset, and Oblique Liners were evaluated in terms of design and geometry to demonstrate that the devices meet performance requirements and are as safe and effective as their predicate. This information and testing data formed the basis for a determination of substantial equivalence.

Specific Non-clinical Testing Completed:

- Liner Push-Out Evaluation
- Liner Lever-Out Evaluation
- Liner Torque-Out Evaluation
- Rim Deformation Testing
- Liner Locking Mechanism Strength Analysis
- Anatomic Fatigue Testing
- Liner Wear Performance
- Liner Durability and Backside Wear
- Temperature Effects on Liner Assembly
- Interaction of MRI with Implants
- Range of Motion Evaluation
- Shell Fatigue and Deformation Evaluation

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Zimmer, Inc.
% Ms. Rebecca M. Brooks
Regulatory Affairs Specialist
P.O. Box 708
Warsaw, Indiana 46581-0708

APR 15 2011

Re: K103662
Trade/Device Name: Continuum and Trilogy Integrated Taper (IT) Acetabular Systems
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, JDI
Dated: March 18, 2011
Received: March 21, 2011

Dear Ms. Brooks:

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,

for

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): K103662

Device Name:

Continuum® and *Trilogy*® Integrated Taper (IT) Acetabular Systems Shells & *Longevity*® IT Highly Crosslinked Polyethylene Elevated, Offset, and Oblique Liners

Indications for Use:

The system is indicated for primary or revision surgery in skeletally mature individuals 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 system is intended for use either with or without bone cement in total hip arthroplasty.

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 M. Melkerson

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

510(k) Number K103662