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

K101229

Zimmer

Summary of Safety and Effectiveness

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708 DEC - 3 2010
Contact Person:	Rebecca Brooks Regulatory Affairs Specialist Telephone: 574.371.8033 Fax: 574.372.4605
Date:	July 12, 2010
Trade Names:	*Longevity*® IT Highly Crosslinked Polyethylene Elevated Liners *Continuum*™ Acetabular System *Trilogy*® Integrated Taper (IT) Acetabular System
Common Name:	Total Hip Prosthesis
Classification Names and References:	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 Devices:	*Continuum*™ and *Trilogy*® Integrated Taper (IT) Acetabular Systems, manufactured by Zimmer Inc., K091508, cleared September 11, 2009. *Longevity*® IT Highly Crosslinked Polyethylene Elevated Liners manufactured by Zimmer Inc., K093846, cleared 04 February 2010.

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Device Descriptions:

The *Longevity* IT Highly Crosslinked Polyethylene Elevated Liners are intended to be used with either *Continuum* or *Trilogy* IT Acetabular components in Total Hip Arthroplasty.

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, optional dome and screw hole plugs

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 Devices:

The *Longevity* IT Highly Crosslinked Polyethylene Elevated Liners and the *Continuum* and *Trilogy* IT Acetabular Systems Shells are packaged, manufactured, and sterilized using equivalent materials and processes as their predicates. The subject device also has the same intended use as the predicate.

The subject devices are line extensions to the previously cleared predicate systems to add 42mm OD shells and additional 22mm, 32mm, and 36mm ID elevated liners. The subject 32mm and 36mm liners are identical to the previously cleared devices; no changes have been made except for the additional sizes. The subject 22mm liner has been modified to include a poly-relief ring above the scallops. The subject 42mm shells have been modified so that they will not accept the option screw hole plugs.

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Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Non-clinical testing was conducted to demonstrate that the subject device performed as intented and met all acceptance criteria. Specific non-clinical testing that was completed includes:

- Wear Performance Analysis
- Anatomic Fatigue Test
- Durability and Backside Wear Analysis
- Lever-Out Strength Test
- Push-Out Strength Test
- Torque-Out Strength Test
- Compatibility in the MR Environment Test

Testing was conducted on the subject devices and compared to the predicate systems. The subject devices functioned as intended and the observed test results exceeded all acceptance criteria. Additionally, an evaluation of the device design and geometry was done, which demonstrated that the Zimmer *Longevity* IT Highly Crosslinked Polyethylene Elevated Liners and the *Continuum* and *Trilogy* IT Acetabular Systems Shells meet performance requirements and are as safe and effective as its predicates. This information and testing data forms 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

DEC - 3 2010

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

Re: K101229
Trade/Device Name: Longevity® IT Highly Crosslinked Polyethylene Elevated Liners, Continuum™ Acetabular System, Trilogy® Integrated Taper (IT) 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
Dated: November 5, 2010
Received: November 8, 2010

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.

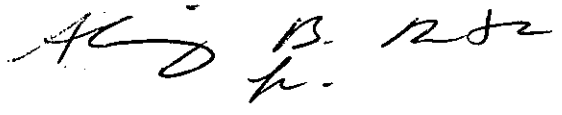
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



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

Enclosure

K101229

Indications for Use

DEC - 3 2010

510(k) Number (if known):

Device Name:

Longevity® IT Highly Crosslinked Polyethylene Elevated Liners
Continuum™ and *Trilogy*® IT Acetabular Systems Shells

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.

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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)

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

510(k) Number K101229