K123019(1/3)

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

OCT 2 2 2012

510k Summary of Safety and Effectiveness

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Rebecca M. Brooks Sr. Specialist, Regulatory Affairs Telephone: (574) 371-8033 Fax: (574) 372-4605
Date:	September 27, 2012
Trade Name:	*Longevity* IT Highly Crosslinked Polyethylene Neutral Liners *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 September 11, 2009 *Longevity* IT Highly Crosslinked Polyethylene Elevated Liners, manufactured by Zimmer, K093846, cleared February 4, 2010 *Continuum* and *Trilogy* IT Acetabular Systems & *Longevity* IT Highly Crosslinked Polyethylene Elevated Liners, manufactured by Zimmer, K101229, cleared December 3, 2010 *Continuum* and *Trilogy* IT Acetabular Systems & *Longevity* IT Highly Crosslinked Polyethylene Elevated, Offset, & Oblique Liners, manufactured by Zimmer, K103662, cleared April 15, 2011
Device Description:	The *Longevity* IT Highly Crosslinked Polyethylene Liners are intended to be used with either *Continuum* or *Trilogy* IT Acetabular components in Total Hip Arthroplasty. The liners are available with neutral, elevated, offset, and oblique liner faces in 28, 32, 36, and 40mm articulation diameters.
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:	No changes are being made to the designs of the subject *Longevity* IT Liners. The proposed modification is limited to expanding the scope of compatible femoral heads. The *Longevity* IT Highly Crosslinked Polyethylene Neutral, Elevated,

Offset, and Oblique Liners are manufactured, packaged, and sterilized using equivalent materials and processes as their predicates. The subject devices also have the same intended use and performance characteristics as their predicates.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Non-clinical testing as well as engineering and risk analyses were performed to demonstrate substantial equivalence of the subject liners to the predicate devices. The specific non-clinical testing and analyses completed include wear testing and range of motion analyses.

The liners were also evaluated in terms of design and geometry to demonstrate that the devices meet performance requirements and are substantially equivalent to their predicates. This information and testing results formed the basis for a determination of substantial equivalence.

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, Incorporated
% Ms. Rebecca M. Brooks
Senior Specialist, Regulatory Affairs
1800 West Center Street
Warsaw, Indiana 46580

OCT 2 2 2012

Re: K123019
Trade/Device Name: Longevity® IT Highly Crosslinked Polyethylene neutral, Offset, and Oblique Liners
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained porous-coat-ed uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, JDI, LZO
Dated: September 27, 2012
Received: September 28, 2012

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

K123019 (1/1)

Indications for Use

510(k) Number (if known):

Device Name:

Longevity® IT Highly Crosslinked Polyethylene Neutral, 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.

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

510(k) Number K123019

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)