K093846

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

FEB - 4 2010

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:	December 14, 2009
Trade Name:	*Longevity*® IT Highly Crosslinked Polyethylene Elevated 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*® Integrated Taper (IT) Acetabular Systems, manufactured by Zimmer Inc., K091508, cleared September 11, 2009.

Device Description:	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 liners are available in 22, 28, 32 and 36mm 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:	The *Longevity* IT Highly Crosslinked Polyethylene Elevated Liners are packaged, manufactured, and sterilized using the same materials and processes as their predicates. The subject device also has the same intended use as the predicate.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: Non-Clinical testing demonstrated that the *Longevity* IT Highly Crosslinked Polyethylene Elevated Liners met performance requirements and are as safe and effective as their predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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

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Re: K093846
Trade/Device Name: Longevity® IT Highly Crosslinked Polyethylene Elevated Liners
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: LZO, JDI, LPH
Dated: January 19, 2010
Received: January 21, 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

K093846

Indications for Use

510(k) Number (if known):

Device Name:

Longevity® IT Highly Crosslinked Polyethylene Elevated 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_ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ____ (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)

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

510(k) Number K093846