DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 13, 2015

Zimmer, Inc.
Mr. Paul Hardy
Specialist, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581

Re: K151448
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, JDI, LZO
Dated: June 12, 2015
Received: June 15, 2015

Dear Mr. Hardy:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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 -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K151448 (page 1/1)

Device Name

Continuum and Trilogy Integrated Taper (IT) Acetabular systems

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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

Summary of Safety and Effectiveness

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Paul Hardy Specialist, Regulatory Affairs Telephone: (574) 372-4257 Fax: (574) 372-4605
Date:	August 11, 2015
Trade Name:	Continuum and Trilogy Integrated Taper (IT) Acetabular Systems including: Continuum IT and Trilogy IT Shells Longevity IT Highly Crosslinked Polyethylene Neutral Liners Longevity IT Highly Crosslinked Polyethylene Elevated Liners
Product Codes / Device:	LPH, JDI, LZO
Regulation Number / Description:	21 CFR § 888.3358- Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented 21 CFR § 888.3350- Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented 21 CFR § 888.3353- Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented
Predicate Devices:	*Continuum* and *Trilogy* Integrated Taper (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

	Longevity Integrated Taper (IT) Highly Crosslinked Polyethylene Elevated Liners, *Continuum* and *Trilogy* Integrated Taper (IT) Acetabular System Shells, manufactured by Zimmer, K101229, cleared December 3, 2010 *Continuum* and *Trilogy* Integrated Taper Highly Crosslinked Polyethylene Elevated, Offset, & Oblique Liners, manufactured by Zimmer, K103662, cleared April 15, 2011
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, optional dome and screw hole plugs, and highly cross-linked polyethylene (HXPE) liners. The shells with screw holes permit the use of previously cleared Tivanium alloy screws to provide additional fixation and security, particularly in those cases where acetabular bone stock is deficient. The dome and screw hole plugs may be placed by the surgeon into any unused holes in the shell.
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:	This submission is for a labeling modification. The labeling modification consists of the addition of Magnetic Resonance Imaging (MRI) compatibility information to the Package Insert, and the application of the “MR Conditional” symbol on the package label.
Performance Data (Nonclinical	Non-Clinical Performance and Conclusions:

and/or Clinical):

The Continuum and Trilogy IT Acetabular Systems have been evaluated for compatibility in the MR environment per Guidance for Industry and FDA Staff, *"Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment."* Based upon the results, the subject device is recommended to bear the "MR Conditional" labeling and include MR compatibility safety information within the package insert.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.