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

November 2, 2016

Zimmer, Incorporated
Mr. Daniel J. Williman
Project Manager, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K133378
Trade/Device Name: Zimmer® Trabecular Metal™ Reverse Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, HSD, KWT, PAO
Dated: March 28, 2014
Received: March 31, 2014

Dear Mr. Williman:

This letter corrects our substantially equivalent letter of May 12, 2014.

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" (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 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,

Lori A. Wiggins -S

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

Enclosure

Indications for Use

510(k) Number (if known): K133378

Device Name:

Zimmer® Trabecular Metal™ Reverse Shoulder System

Indications for Use:

The Trabecular Metal™ Reverse Shoulder System Vivacit-E™ Vitamin E Highly Crosslinked Polyethylene Liners are indicated for:

- x the treatment of severe pain or significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint;
- x ununited humeral head fractures of long duration;
- x irreducible 3-and 4-part proximal humeral fractures;
- x avascular necrosis of the humeral head, or other difficult clinical management problems (such as a failed total shoulder arthroplasty or grossly rotator cuff deficient joint) where arthrodesis or resectional arthroplasty is not acceptable.

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)

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zimmer

510(k) Summary

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Dan Williman Project Manager, Regulatory Affairs Telephone: (574) 371-8065 Fax: (574) 372-4605
Date:	March 28, 2014
Trade Name:	*Zimmer® Trabecular Metal™* Reverse Shoulder System
Common Name:	Reverse Shoulder Poly Liner
Classification Names and References:	Prosthesis, shoulder, semi-constrained, metal/polymer cemented (KWS), Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis (HSD), Shoulder joint metal/polymer non-constrained cemented prosthesis (KWT), Prosthesis, shoulder, semi-constrained, metal/polymer + additive, cemented prosthesis (PAO) (21 CFR 888.3660, 888.3690, 888.3650)
Classification Panel:	Orthopedics/87
Predicate Device(s):	*Zimmer® Trabecular Metal™* Reverse Shoulder System, manufactured by Zimmer, Inc., K052906, cleared December 19, 2005, and K121543, cleared October 11, 2012.
Purpose and Device Description	The *Zimmer Trabecular Metal* Reverse Shoulder System *Vivacit-E* Vitamin E Highly Crosslinked Polyethylene Liners are a series of liners manufactured from Vitamin E (α-tocopherol) blended, highly crosslinked ultrahigh molecular weight polyethylene (HXPE) and are designed for use with the *Zimmer Trabecular Metal* (TM) Reverse Shoulder System in the reverse shoulder application. The liners provide a bearing interface between the TM Reverse Humeral Stem and the glenosphere component. They are offered in two different diameters (36mm and 40 mm) and three thicknesses (+0mm, +3mm and +6mm). The liners

	are also offered as either 60° standard liners or 65° retentive liners. The retentive liners cover a larger surface of the glenosphere component.
Intended Use:	The Trabecular Metal™ Reverse Shoulder System Vivacit-E™ Vitamin E Highly Crosslinked Polyethylene Liners are indicated for: • the treatment of severe pain or significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint; • ununited humeral head fractures of long duration; • irreducible 3-and 4-part proximal humeral fractures; • avascular necrosis of the humeral head, or other difficult clinical management problems (such as a failed total shoulder arthroplasty or grossly rotator cuff deficient joint) where arthrodesis or resectional arthroplasty is not acceptable.
Comparison to Predicate Device:	The proposed devices are identical to the predicate except for the material used for the *Vivacit-E* liner, and locking mechanism dimensional changes, which have been made to both the proposed Conventional UHMWPE liner and the proposed *Vivacit-E* liner.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: The results of non-clinical (lab) performance testing demonstrate that the devices are safe and effective for their intended use and substantially equivalent to the predicate devices. Testing/analysis performed included: locking mechanism test, torque test, fatigue test, subluxation test, Ethylene Oxide residual analysis, wear and magnetic resonance interaction evaluation. Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device.