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. Anthony Francalancia
Senior Specialist, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581

Re: K121543
Trade/Device Name: Zimmer Trabecular Metal 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, KWT, KWS, HSD
Dated: August 31, 2012
Received: September 4, 2012

Dear Mr. Francalancia:

This letter corrects our substantially equivalent letter of October 11, 2012.

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

K121543(1/1)

Indications for Use

510(k) Number (if known): K121543

Device Name:

Zimmer Trabecular Metal Shoulder System

Indications for Use:

The *Zimmer Trabecular Metal* Shoulder System is indicated for the following:

Hemiarthroplasty/Total application:

- 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 where arthrodesis or resectional arthroplasty is not acceptable.

Reverse application:

- 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.

The assembled humeral component may be used alone for hemiarthroplasty or combined with the glenoid component or reverse components for total shoulder arthroplasty (conventional or reverse applications).

The humeral components are intended for either cemented or uncemented use. The reverse base plate is intended for uncemented use, and requires two screws for fixation. When used in a total shoulder application, the all-polyethylene glenoid components are intended for cemented use only. In the USA, the *Trabecular Metal* Glenoid must be cemented under the base (see surgical technique for details) or fully cemented in place.

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)

Peter G Pollen for Anton Dmitriev

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

510(k) Number K121543

K121593 (1/3)

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

OCT 11 2012

Summary of Safety and Effectiveness

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Anthony Francalancia Senior Specialist, Regulatory Affairs Telephone: (574) 372-4570 Fax: (574) 372-4605
Date:	October 11, 2012
Trade Name:	*Zimmer® Trabecular Metal™* (TM) Reverse Shoulder System, Base Plates and Humeral Stems
Product Code / Device:	KWT - Shoulder joint metal/polymer non-constrained cemented prosthesis. KWS - Shoulder joint metal/polymer semi-constrained cemented prosthesis. HSD – Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.
Regulation Number / Description:	21 CFR § 888.3650 - Shoulder joint metal/polymer non-constrained cemented prosthesis. 21 CFR § 888.3660 - Shoulder joint metal/polymer semi-constrained cemented prosthesis. 21 CFR § 888.3690 - Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.
Predicate Device:	*Zimmer Trabecular Metal* Reverse Shoulder System, manufactured by Zimmer, K052906, cleared December 19, 2005. *Zimmer Trabecular Metal* Reverse Shoulder System, manufactured by Zimmer, K060704, cleared May 19, 2006.
Device Description:	The proposed Base Plates and Humeral Stems are a line extension of the *Zimmer Trabecular Metal* Reverse Shoulder System, which consists of conventional and reverse, semi- and non-

K121543 (2/3)

constrained shoulder prostheses for total or hemi-arthroplasty applications.

Intended Use:

The *Zimmer Trabecular Metal* Shoulder System is indicated for the following:

Hemiarthroplasty/Total application:

- 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 where arthrodesis or resectional arthroplasty is not acceptable.

Reverse application:

- 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.

The assembled humeral component may be used alone for hemiarthroplasty or combined with the glenoid component or reverse components for total shoulder arthroplasty (conventional or reverse applications).

	The humeral components are intended for either cemented or uncemented use. The reverse base plate is intended for uncemented use, and requires two screws for fixation. When used in a total shoulder application, the all-polyethylene glenoid components are intended for cemented use only. In the USA, the *Trabecular Metal* Glenoid must be cemented under the base (see surgical technique for details) or fully cemented in place.
Comparison to Predicate Device:	The proposed devices are line extensions to the predicate devices. They share the same indications for use/intended use, utilize the same materials and manufacturing processes, and have similar technical features as their predicates.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: Performance testing was conducted on the proposed devices per FDA's *Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement.* Also, testing/analysis were performed to evaluate the safety of the device based on risks identified in Zimmer's Design Failure Mode Effects Analysis (DFMEA). This included fatigue testing/analysis of the Base Plate and the Humeral Stems. Additionally, micro-motion and screw pullout forces were analyzed/compared between the predicate base plate and the proposed base plate with increased lateral offset. Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device.