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 Warsaw, IN 46581-0708
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DEC 03 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
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Date: August 31, 2012

Trade Name: *Zimmer® Trabecular Metal™* (TM) Reverse
 Shoulder System, Non-Porous 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 Non-Porous Humeral Stems are a line
 extension of the *Zimmer Trabecular Metal* Reverse
 Shoulder System, which consists of conventional
 and reverse, semi- and non-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. Outside the USA the *Trabecular Metal* Glenoid may be used without cement (pressfit).

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 material and manufacturing processes, and have similar technical features as their predicates. The proposed devices differ from the predicate humeral stems in that the proposed devices do not have Trabecular Metal in the proximal region of the stem.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Performance testing was conducted on the proposed devices to evaluate the safety of the device based on risks identified in Zimmer's Design Failure Mode Effects Analysis (DFMEA). This included fatigue testing, and stability testing.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 3, 2012

Zimmer, Incorporated
% Mr. Anthony Francalancia
Senior Specialist, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581

Re: K122692

Trade/Device Name: Zimmer Trabecular Metal Reverse Shoulder System
Regulation Number: 21 CFR 888.3650
Regulation Name: Shoulder joint metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWT, KWS, HSD
Dated: August 31, 2012
Received: September 4, 2012

Dear Mr. Francalancia

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

Page 2 – Mr. Anthony Francalancia

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" (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 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,

Erin I. Keith

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): K122692

Device Name:

Zimmer® Trabecular Metal™ (TM) Reverse Shoulder System, Non-Porous Humeral Stems

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Reverse application:

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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)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

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