November 30, 2017

Zimmer, Inc.
Andrew Steward
Regulatory Affairs Specialist
56 East Bell Drive
Warsaw, Indiana 46581

Re: K172767
Trade/Device Name: Zimmer Trabecular Metal Reverse Shoulder System, Mini Glenoid
Regulation Number: 21 CFR 888.3650
Regulation Name: Shoulder Joint Metal/Polymer Non-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: PHX, KWT, KWS, HSD
Dated: September 21, 2017
Received: September 13, 2017

Dear Andrew Steward:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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)*
K172767

Device Name
Zimmer® Trabecular Metal™ Reverse Shoulder System, Mini Glenoid

Indications for Use *(Describe)*
The Zimmer Trabecular Metal Shoulder System is indicated for the following:
Hemiarthroplasty/Anatomic 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 initial 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.

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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510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the *Zimmer® Trabecular Metal™* Reverse Shoulder System, Base Plate Enhancement 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor:
Zimmer, Inc.
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Warsaw, IN 46580
Establishment Registration Number: 1822565

Contact Person:
Andrew Steward
Regulatory Affairs Specialist
Telephone: (574) 372-6829
Fax: (574) 372-3975

Date: September, 11 2017

Trade Name: Zimmer® Trabecular Metal™ Reverse Shoulder System, Mini Glenoid

Classification Name:
PHX – Shoulder joint metal/polymer semi-constrained cemented prosthesis. (21 CFR 888.3660)
KWS – Shoulder joint metal/polymer semi-constrained cemented prosthesis. (21 CFR 888.3660)
KWT – Shoulder joint metal/polymer non-constrained cemented prosthesis. (21 CFR 888.3650)
HSD – Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis. (21 CFR 888.3690)

Predicate Device(s):

Device	Manufacturer	510(k) Number
Zimmer® Trabecular Metal™ Reverse Shoulder System, Base Plates and Humeral Stems	Zimmer, Inc.	K121543

Purpose and Device Description:

The proposed devices are a line extension of the *Zimmer® Trabecular Metal™* Reverse Shoulder System, which consists of conventional (anatomic) and reverse, semi- and non-constrained shoulder prostheses for total or hemiarthroplasty applications.

Intended Use and Indications for Use:

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

Hemiarthroplasty/Anatomic 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;
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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 initial 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.

Summary of Technological Characteristics:

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** The intended use is identical to those cleared in K121543.
- **Indications for Use:** The indications for use are identical to those cleared in K121543.

- **Materials:** The baseplate (*Tivanium*®, *Trabecular Metal*™) and glenosphere (*Zimaloy*) materials are the same as the predicate devices cleared via K121543.
- **Design Features:** The design features of the subject device are similar to those in currently marketed devices cleared in K121543. The design differences have not identified any issues that would impact the safety and efficacy of the devices.
- **Sterilization:** The implants are offered to the user in the sterile configuration by gamma irradiation. The instruments are offered to the user in the non-sterile configuration and will be required to be steam sterilized by the user prior to use. The sterilization method is the same as that used for the predicate devices cleared via K121543.

Summary of Performance Data (Nonclinical and/or Clinical):

- **Non-Clinical Tests:** Non-clinical testing demonstrated that the proposed devices meets performance requirements as defined by Design Control activities and is substantially equivalent to the predicate device in terms of safety and efficacy.

  1. Diffusion Bonding
  2. Accelerated Corrosion Fatigue
  3. Initial Fixation Stability
  4. MRI Compatibility Evaluation
  5. Glenosphere Fatigue
  6. Baseplate Fatigue
  7. Axial Taper Connection
  8. Torsional Taper Connection
  9. Wear Assessment
  10. Range of Motion Evaluation
  11. Glenosphere Removal

- **Clinical Tests:** Clinical data and conclusions were not needed for this device.

Substantial Equivalence Conclusion:

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. No new issues of safety and efficacy have been raised.