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

Zimmer, Incorporated
Ms. Dorothy Snyder
Associate Director, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

November 24, 2015

Re: K152841
Trade/Device Name: Zimmer Plates and Screws System (ZPS) – Sterile 2.7mm Cortical Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: September 28, 2015
Received: September 29, 2015

Dear Ms. Snyder:

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 Parts 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,

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)*
K152841

Device Name
Zimmer Plates and Screws System (ZPS) - Sterile 2.7mm Cortical Screws

Indications for Use *(Describe)*
ZPS One-Third Tubular Plates, One-Quarter Tubular Plates, T-Plates, L-Buttress Plates, Cobra Plates, Semi-Tubular Plates, Symphyseal Bridge Plates, Reconstruction Plates, Contourable Dual Compression Plates, Cloverleaf and Spoon Plates are indicated for temporary internal fixation and stabilization of osteotomies and fractures, such as:

- comminuted fractures
- supracondylar fractures
- extra-articular fractures
- fractures in osteopenic bone
- nonunions
- malunions

Smaller-sized ZPS plates are used for small bones and small fragments of the hands and feet.

ZPS Calcaneal plates are indicated for temporary internal fixation and stabilization of osteotomies and fractures of the calcaneus. ZPS and Forte Screws are temporary internal fixation devices designed to stabilize fractures during the normal healing process.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

510(k) Summary

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Dorothy Snyder Associate Director, Trauma Regulatory Affairs Telephone: (574) 372-4092 Fax: (574) 372-4605
Date:	November 16, 2015
Trade Name:	*Zimmer*® Plates and Screws (ZPS) Sterile 2.7mm Cortical Screw
Common Name:	Temporary Internal Fixation Devices
Classification Names and References:	Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040, HWC)
Classification Panel:	Orthopedics/87
Predicate Device(s):	*Zimmer*® Plates and Screws, Non-sterile 2.7mm cortical screws cleared under K143066 on November 28, 2014. Zimmer Plates and Screws System (ZPS) – Non-sterile ZPS cleared under K143331 on March 04, 2015 Reference Predicate Only: Universal Locking System, Sterile 2.7mm cortical screws cleared under K063303 on November 22, 2006.
Purpose and Device Description	The purpose of this submission is a line extension adding the sterile version of the 2.7mm cortical screws cleared under K143066. <u>System Description</u> The Zimmer Plates and Screws System (ZPS) is a nonlocking, stainless steel plate and screw system. Plate

	shapes vary to address varying patient bone sizes and injury fragment sizes. Plates incorporate a spherical sliding slope plate hole design to achieve the compression required to treat bone fractures. The plates are used with a variety of screws for temporary fixation to the bone. The ZPS Washers are intended to prevent a screw head from breaking through the cortex of the bone by distributing the forces/load over a larger area when used for non-plate, bone fragment, and fracture fixation
Intended Use:	ZPS One-Third Tubular Plates, One-Quarter Tubular Plates, T-Plates, L-Buttress Plates, Cobra Plates, Semi-Tubular Plates, Symphyseal Bridge Plates, Reconstruction Plates, Contourable Dual Compression Plates, Cloverleaf and Spoon Plates are indicated for temporary internal fixation and stabilization of osteotomies and fractures, such as: • comminuted fractures • supracondylar fractures • extra-articular fractures • fractures in osteopenic bone • nonunions • malunions Smaller-sized ZPS plates are used for small bones and small fragments of the hands and feet. ZPS Calcaneal plates are indicated for temporary internal fixation and stabilization of osteotomies and fractures of the calcaneus. ZPS and Forte Screws are temporary internal fixation devices designed to stabilize fractures during the normal healing process.
Comparison to Predicate Device:	The subject ZPS screws are identical in intended use, basic shape, compatible diameters, materials and performance characteristics to their respective predicate devices, with exception that the subject screws will be provided sterile.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: • **Shelf Life -** The implants that are supplied sterile have a 10 year shelf life. Zimmer performs shelf life testing based on FDA recognized consensus standards ISO 11607-1:2006 and 11607-2:2006.

- **Biocompatibility** – Biocompatibility testing on the screw material was conducted per ISO 10993-1 and Good Laboratory Practices (21 CFR 58). All testing passed.

- **Performance Evaluation** – Because the sterile 2.7mm ZPS screws are identical to the sterile version cleared under K063303 and identical (with exception to sterility) to those non-sterile screws cleared K143066, no additional mechanical testing was performed.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for these devices to show substantial equivalence.