



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 12, 2014

Zimmer, Incorporated
Stephen H. McKelvey, MA, RAC
Senior Project Manager, Trauma Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K142836

Trade/Device Name: Non-sterile Zimmer Plates and Screws System (ZPS)
Compression/Reconstruction/Symphyseal Plates and Forte
Cancellous Screws

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and
accessories

Regulatory Class: Class II

Product Code: HRS, HWC

Dated: September 26, 2014

Received: September 30, 2014

Dear Mr. McKelvey:

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

Page 2 – Mr. Stephen H. McKelvey, MA, RAC

(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" (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 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) K142836

K142836

Device Name

Non-sterile Zimmer Plates and Screws System (ZPS) Compression/Reconstruction/Symphyseal Plates and Forte Cancellous Screws

Indications for Use (Describe)

ZPS One-Third Tubular Plates, T-Plates, Semi-Tubular Plates, Symphyseal Bridge Plates, Reconstruction Plates, and Contourable Dual Compression 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)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Sponsor: Zimmer, Inc.
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Contact Person: Stephen H. McKelvey
Senior Project Manager, Trauma Regulatory Affairs
Telephone: (574) 372-4944
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Date: September 26, 2014

Trade Name: Non-sterile *Zimmer*[®] Plates and Screws System (ZPS)
Compression/Reconstruction/Symphyseal Plates and Forte
Cancellous Screws

Common Name: Temporary Internal Fixation Devices

Classification Names and References: Single/multiple component metallic bone fixation
appliances and accessories (21 CFR 888.3030, Product
Code HRS) and Smooth or threaded metallic bone fixation
fastener (21 CFR 888.3040, Product Code HWC)

Classification Panel: Orthopedics/87

Predicate Device(s): Synthes 2.0mm DCP Plate (K001941, cleared September
22, 2000), Synthes 3.5mm Curved Recon (K042377,
cleared October 07, 2004), *Zimmer* ULS 2.7mm Straight
Recon Plate (K063303, cleared November 22, 2006)
Zimmer ZPS 3.5mm T-Plate (K140508, cleared August
14, 2014), *Zimmer* Forte Cancellous Screws (K112885,
cleared December 19, 2011)

Purpose and Device Description: The ZPS System is a non-locking, 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 Forte Cancellous Screws are used with the
ZPS Plates to form a fixation construct.

Intended Use:

ZPS One-Third Tubular Plates, T-Plates, Semi-Tubular Plates, Symphyseal Bridge Plates, Reconstruction Plates, and Contourable Dual Compression 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 Plates and subject Forte Screws are similar in intended use, basic shape, compatible diameters, materials and performance characteristics to their respective predicate devices. The subject devices are provided non-sterile.

Performance Data (Nonclinical and/or Clinical):Non-Clinical Performance and Conclusions:

- Biocompatibility - Biocompatibility testing on the ZPS Plate and Forte Screw material was conducted per ISO 10993-1 and Good Laboratory Practices (21 CFR § 58). All testing passed.
- Comparative static and fatigue testing along with beam bending cross sectional analyses of the ZPS Plates and their respective predicate devices, Synthes 2.0mm DCP Plate (K001941), Synthes 3.5mm Curved Recon (K042377), Zimmer ULS 2.7mm Straight Recon Plate (K063303), Zimmer ZPS 3.5mm T-Plate (K140508), resulted in similar mechanical properties. The subject and predicate devices are substantially equivalent.

- Except for the sterilization status, the subject non-sterile Forte screws are identical to the sterile Forte screws cleared in K112885.

Clinical Performance and Conclusions:

- Clinical data and conclusions were not needed for these devices.