**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

February 23, 2015

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

Re: K150121
Trade/Device Name: Zimmer® Periarticular Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: January 16, 2015
Received: January 20, 2015

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 (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

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)* K150121

Device Name

Zimmer Periarticular Plating System

Indications for Use *(Describe)*

Periarticular Plating System plates are indicated for temporary internal fixation and stabilization of osteotomies and fractures, including: comminuted fractures, supracondylar fractures, intra-articular and extra-articular condylar fractures, fractures in osteopenic bone, nonunions, and malunions.

Periarticular Plating System Small Distal Volar Radial Radius and Small Distal Volar Ulnar Radius plates are indicated for temporary internal fixation and stabilization of fractures and osteotomies of the volar aspect of the distal radius, including associated carpal fusions.

Periarticular Plating System Calcaneal plates are indicated for complex extra-articular and intra-articular fractures and osteotomies of the calcaneus.

Periarticular Plating System 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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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P.O. Box 708
Warsaw, IN 46581-0708
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## 510(k) Summary

**Sponsor:**

Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

**Contact Person**:

Stephen H. McKelvey
Senior Project Manager, Trauma Regulatory Affairs
Telephone: (574) 372-4944
Fax: (574) 372-4605

**Date:**

January 16, 2015

**Trade Name:**

*Zimmer*® Periarticular Plating System

**Common Name:**

Periarticular Non-locking Plates

**Classification Names and References:**

Single/ Multiple Component Metallic Bone Fixation Appliances and Accessories, 21 CFR 888.3030 (HRS)

**Classification Panel:**

Orthopedics/87

**Predicate Devices:**

*Zimmer* Plates and Screws System (K140508, K143066)
*Zimmer* Universal Locking System (K063303)

**Purpose and Device Description:**

The *Zimmer* Periarticular Plating System consists of temporary implants for the management of periarticular bone fractures through interfragmentary compression and bone plating. This submission covers various sizes of femoral, tibial, fibular, femoral, humeral, ulnar, and radial plates.

**Indications for Use:**

Periarticular Plating System plates are indicated for temporary internal fixation and stabilization of osteotomies and fractures, including: comminuted fractures, supracondylar fractures, intra-articular and extra-articular condylar fractures, fractures in osteopenic bone, nonunions, and malunions.

Periarticular Plating System Small Distal Volar Radial Radius and Small Distal Volar Ulnar Radius plates are indicated for temporary internal fixation and stabilization of fractures and osteotomies of the volar aspect of the distal radius, including associated carpal fusions.

Periarticular Plating System Calcaneal plates are indicated for complex extra-articular and intra-articular fractures and osteotomies of the calcaneus.

Periarticular Plating System screws are temporary internal fixation devices designed to stabilize fractures during the normal healing process.

**Comparison to Predicate Device:**

The *Zimmer* Periarticular Plating System plates covered by this submission are substantially equivalent to the predicate devices, in that they have the same intended use, function, and fundamental scientific technology. The differences between the subject and predicate devices do not raise new issues of safety or effectiveness.

**Performance Data (Nonclinical and/or Clinical):**

*Non-Clinical Performance and Conclusions*:

- **Shelf Life -** Accelerated aging testing conducted shows that the sterile devices included in this submission have a shelf life of 10 years.

- **Biocompatibility** – Biocompatibility testing of the subject implant devices was conducted per ISO 10993-1 and Good Laboratory Practices (21 CFR 58). All testing passed.

- **Performance Testing** – Engineering analysis demonstrates the devices are safe and effective and substantially equivalent to the predicate devices.

Conclusions: The non-clinical performance data presented in this submission show the subject devices will perform in a substantially equivalent manner to the predicate devices.

*Clinical Performance and Conclusions*:

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