



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

Zimmer, Incorporated
Ms. Dalene Binkley
Senior Specialist, Trauma Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581

January 28, 2016

Re: K151716

Trade/Device Name: *Cable-Ready*[®] Cable Grip System: *Cable-Ready*[®] Bone Plate 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, JDQ

Dated: December 23, 2015

Received: December 28, 2015

Dear Ms. Binkley:

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,

Mark N. Melkerson -S

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)

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Device Name

Cable-Ready® Cable Grip System: Cable-Ready® Bone Plate System

Indications for Use (Describe)

Cable-Ready® Bone Plate System: The Cable-Ready® Bone Plate with Cerclage Cable is indicated for use where wire, cable, or band cerclage is used in combination with bone plates to provide fixation and/or stabilization of long bones - femur, tibia and humerus. Examples include periprosthetic fractures or bone loss, comminuted shaft fractures, and nonunions of previous fractures with or without failed hardware.

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.

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510(k) Summary

Sponsor: Zimmer, Inc.
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Contact Person: Dalene T. Binkley
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Date: July 7, 2015

Trade Name: *Cable-Ready*[®] Cable Grip System: *Cable-Ready*[®] Bone Plate System

Common Name: Plate, Fixation, Bone
Cerclage, Bone Fixation

Classification Names and References: Plate, Fixation, Bone:
Regulation Number: CFR 888.3030
Classification Number: 87 HRS

Cerclage, Fixation:
Regulation Number: CFR 888.3010
Classification Number: 87 JDQ

Classification Panel: Orthopedics/87

Predicate Device(s): Pioneer Laboratories Bone Plate with Cerclage Cable,
Pioneer Laboratories, K940729, cleared December 27,
1994

Pioneer Laboratories Bone Plate with Cable's Device,
Pioneer Laboratories, K972223, cleared September 10,
1997

Purpose and Device Description:

The *Cable-Ready*® Bone Plate System is used to address complicated fractures and reconstruction of the long bones - femur, tibia and humerus. These devices are used as a compressive force to aid the surgeon in containing fracture fragments as they heal. The plate is placed on the bone and secured with a multifilament cable that is inserted into the plate and passed around the bone to the other side of the plate where it is attached and tightened, securing the fracture(s) in place. Cortical bone screws are used for additional fixation as needed.

The bone plates are offered in 3 lengths – 187mm (6 holes), 246mm (8 holes) and 305mm (10 holes). The cerclage cable is 1.8mm in diameter and 610mm in length. Both the bone plates and cable are manufactured from 316L stainless steel.

Intended Use:

Cable-Ready® Bone Plate System:

The *Cable-Ready*® Bone Plate with Cerclage Cable is indicated for use where wire, cable, or band cerclage is used in combination with bone plates to provide fixation and/or stabilization of long bones – femur, tibia and humerus. Examples include periprosthetic fractures or bone loss, comminuted shaft fractures, and nonunions of previous fractures with or without failed hardware.

Comparison to Predicate Device:

The *Cable-Ready*® Bone Plate System is similar in intended use, materials, basic shape and performance characteristics to the predicate devices.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

- Biocompatibility – Biocompatibility testing on the *Cable-Ready* Bone Plates and Cerclage Cable materials was conducted per ISO 10993-1 and Good Laboratory Practices (21 CFR § 58). All testing passed.
- Performance Evaluation – The engineering analysis establishes that the difference in length, number of screw holes and crimp mechanism between the subject devices

and the predicate devices do not affect the clinical strength of the subject bone plates and cable.

Conclusions: The data presented in this submission demonstrates that the subject devices are substantially equivalent to the predicate devices.

Clinical Performance and Conclusions:

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