



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

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

January 15, 2016

Re: K151848

Trade/Device Name: *Cable-Ready*® Cable Grip System: *Cable-Ready* Pin System, *Cable-Ready* Needle System

Regulation Number: 21 CFR 888.3010

Regulation Name: Bone fixation cerclage

Regulatory Class: Class II

Product Code: JDQ, HWC

Dated: December 15, 2015

Received: December 17, 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® Pin System

Indications for Use (Describe)

The Cable-Ready® Pin System is indicated for use in olecranon fractures, patellar fractures, proximal humerus fractures, greater tuberosity humerus fractures, and medial malleolus tibial fractures where fractures may not be securely held by either a bone screw, bone pin, cable, or cerclage cable alone.

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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PRASStaff@fda.hhs.gov

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Indications for Use

510(k) Number (if known)

K151848 (page 2 of 2)

Device Name

Cable-Ready® Cable Grip System: Cable-Ready® Needle System

Indications for Use (Describe)

The Cable-Ready® Needle System is indicated for securing fractures of the olecranon, patella, humerus, shoulder and ankle, reducing and securing acromioclavicular dislocations as well as sternotomy surgery.

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)

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510(k) Summary

Sponsor: Zimmer, Inc.
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Warsaw, IN 46581-0708

Contact Person: Dalene Binkley, MS, RAC
Senior Specialist, Trauma Regulatory Affairs
Telephone: 574-372-4970
Fax: (574) 371-8760

Date: January 13, 2016

Trade Name: This is a bundled traditional 510(k). The two systems bundled in this submission are:

Cable-Ready[®] Cable Grip System:

1) *Cable-Ready* Pin System
2) *Cable-Ready* Needle System

Common Name: Cerclage Cable and Bone Screw

Classification Names and References: Bone Fixation Cerclage
21 CFR 888.3010, JDQ

Smooth or threaded metallic bone fixation fastener
21 CFR 888.3040, HWC

Classification Panel: Orthopedics/87

Predicate Device(s): Pioneer Laboratories Cable Pin (Pioneer Surgical Technology, K941174, cleared 9/19/94)

Zimmer[®] Kirschner Wires and Steinmann Pins (Zimmer, Inc., K143618, cleared 2/6/15)

Suture Wire and Wire Loops (Zimmer, Inc. K150889, cleared 7/1/15)

Songer Cable System, Modification (Pioneer Surgical Technology, K935481, cleared 1/26/94)

Device Description:

Zimmer is requesting clearance for modifications to the *Cable-Ready* Cable Grip System: *Cable-Ready* Pin System and *Cable-Ready* Needle System. The subject devices are similar in that they are both 1.3mm cables used in reconstructive and trauma surgery, securing bone fractures. The stainless steel *Cable-Ready* Pin System has a partially threaded 4.0mm cancellous lag screw (pin), available in differing lengths, attached to the cable which is implanted into the bone. The *Cable-Ready* Needle System has a curved stainless steel surgical needle attached to either a stainless steel or titanium leader and cable that is passed through the bone. The needle is cut off once the fracture is secure. Both systems' cables utilize the same instruments to secure the crimp and trim off excess.

Intended Use:***Cable-Ready* Pin System:**

The *Cable-Ready* Pin System is indicated for use in olecranon fractures, patellar fractures, proximal humerus fractures, greater tuberosity humerus fractures, and medial malleolus tibial fractures where fractures may not be securely held by either a bone screw, bone pin, cable, or cerclage cable alone.

***Cable-Ready* Needle System:**

The *Cable-Ready* Needle System is indicated for securing fractures of the olecranon, patella, humerus, shoulder and ankle, reducing and securing acromioclavicular dislocations as well as sternotomy surgery.

Comparison to Predicate Device:

The subject devices incorporate similar or identical materials, similar or identical indications for use, similar or identical sizes of implants, and the same technological characteristics as the predicate devices.

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 devices was conducted per ISO 10993-1 and

Good Laboratory Practices (21 CFR 58). All testing passed.

- **Performance Evaluation** – A combination of performance testing - static, fatigue, torque and pullout testing for the cable pin and engineering analyses for the cable needle demonstrate the subject devices are safe and effective and substantially equivalent to the predicate devices.

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

Clinical Performance and Conclusions:

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