



Food and Drug Administration
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July 1, 2015

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

Re: K150889
Trade/Device Name: Suture Wires and Wire Loops
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: JDQ
Dated: May 26, 2015
Received: May 28, 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 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" (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,

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)

K150889

Device Name

Suture Wires and Wire Loops

Indications for Use (Describe)

Suture wires and wire loops are indicated for use for bone fracture fixation, osteotomy, arthrodesis, correction of deformity, revision procedures where other treatments or devices have been unsuccessful, and bone reconstruction procedures.

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: Dorothy A. Snyder
Associate Director, Regulatory Affairs
Telephone: (574) 372-4092
Fax: (574) 371-8760

Date: March 23, 2015

Trade Name: Suture Wires and Wire Loops

Common Name: Suture Wires and Wire Loops

Classification Names and References: Cerclage, fixation (JDQ) per 21 § CFR 888.3010, Bone fixation cerclage

Classification Panel: Orthopedics/87

Predicate Device(s): Ortho Solutions Limited, Ortho Solutions Trauma Implants for Osteosynthesis, Cerclage Wires (K110895 – cleared 12/19/2011)

Purpose and Device Description: Suture wires and wire loops are used for bone fracture fixation during the healing process. These wires are available in multiple diameters and lengths.

Intended Use: Suture wires and wire loops are indicated for use for bone fracture fixation, osteotomy, arthrodesis, correction of deformity, revision procedures where other treatments or devices have been unsuccessful, and bone reconstruction procedures.

Comparison to Predicate Device: The Zimmer suture wires and wire loops are identical in intended use and similar in 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 suture wire and wire loop materials was conducted per ISO 10993-1 and Good Laboratory Practices (21 CFR § 58). All testing passed.
- Performance Evaluation – The engineering analysis shows the bending strength of the subject devices is substantially equivalent to the predicate devices. The evaluation shows the differences in materials, diameter and length between the subject devices and the predicate devices do not affect the clinical strength of the subject suture wires and wire loops.

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.