July 5, 2019

Zimmer, Inc
Annette Minthorn
Sr. Specialist, Regulatory Affairs
PO Box 708
Warsaw, Indiana 46581-0708

Re: K191238
Trade/Device Name: Zimmer® Guide Wire Devices
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: May 6, 2019
Received: May 8, 2019

Dear Annette Minthorn:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For CAPT Raquel Peat, PhD, MPH, USPHS
Director
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191238

Device Name
Zimmer® Guide Wire Devices

Indications for Use *(Describe)*
The subject guide wire devices are instruments intended to assist in fracture fixation and stabilization of long bones during the surgical procedure of intramedullary nailing. The implant specific instruments are to be used with the Zimmer® Natural Nail® System and Zimmer® M/DN® Intramedullary Fixation System.

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.

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

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510(k) Summary
Traditional 510(k)

510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Zimmer Guide Wires 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor:

Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708
Establishment Registration Number: 1822565

Contact Person:

Annette Minthorn
Sr. Specialist, Regulatory Affairs
Telephone: (574-372-4294)
Fax: (574-372-4644)

Date:

05 July 2019

Subject Device:

Trade Name:

- Zimmer® Guide Wire Devices

Common Name:

- Zimmer® Guide Wires

Classification Name:

- HSB– Rod, Fixation, Intramedullary and Accessories (21 CFR 888.3020)

Predicate Device(s):

- K142281 Zimmer® M/DN Intramedullary Fixation System, (Zimmer, Inc.)
- K101622 Zimmer® Natural Nail™ System – Retrograde Femoral Nail (Zimmer, Inc.)

510(k) Summary
Traditional 510(k)

Purpose and Device Description:

- The purpose of this submission is to request clearance for the packaging change and classification of the subject guide wire instruments. These instruments are used to assist in fracture fixation and stabilization of long bones during the surgical procedure of intramedullary nailing. The guide wires are made of either L605 Cobalt-Chrome-Tungsten-Nickel Alloy (per ASTM F90) or 316L Stainless Steel (per ASTM F138). These instruments will be provided sterile by Gamma Radiation.

Intended Use and Indications for Use:

- **Intended Use:** To assist in fracture fixation and stabilization of long bones during the surgical procedure of intramedullary nailing.
- **Indications for Use:** The subject guide wire devices are instruments intended to assist in fracture fixation and stabilization of long bones during the surgical procedure of intramedullary nailing. The implant specific instruments are to be used with the Zimmer® Natural Nail® System and Zimmer® M/DN® Intramedullary Fixation System.

Summary of Technological Characteristics:

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** To assist in fracture fixation and stabilization of long bones during the surgical procedure of intramedullary nailing.
- **Indications for Use:** The subject guide wire devices are instruments intended to assist in fracture fixation and stabilization of long bones during the surgical procedure of intramedullary nailing. The implant specific instruments are to be used with the Zimmer® Natural Nail® System and Zimmer® M/DN® Intramedullary Fixation System.
- **Materials:** L605 Cobalt-Chrome-Tungsten-Nickel Alloy and 316L Stainless Steel
- **Design Features:** The design features of the subject guide wires are similar to those in the currently marketed

devices cleared in K142281 and K101622. The design differences have not identified any issues that would impact the safety and effectiveness of the device.

- **Sterilization:** The instruments are offered to the end user in the sterile configuration. They will be sterilized using Gamma sterilization.

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  - **Bench Testing and Conclusions** conducted on the proposed devices are summarized below:
    - Packaging Design Verification Protocol for the G6531 Group and G6532 Group (Reports): These test verified that the proposed G6531/G6532 pouch packaging system maintains integrity of the sterile barrier system through hazards of global distribution for the proposed 70/100cm devices and is statistically equivalent to that of the predicate devices per *ASTM F2096, ASTM F88, ASTM F1886, and ASTM D4169.*

    - Conclusions: The data presented in this submission show that the changes do not affect the safety and/or effectiveness of the subject devices and that the subject devices will perform in a substantially equivalent manner to the predicate devices.

- **Clinical Performance and Conclusions:**
  - Clinical data and conclusions were not needed for these devices to show substantial equivalence.
- **Animal Testing and Conclusions:**
  - Animal data and conclusions were not needed for these devices to show substantial equivalence.

Substantial Equivalence Conclusion

The subject guide wire devices have shown to be substantially equivalent to the predicate devices. Results of the non-clinical tests indicate that the device will perform within the intended uses and no new issues of safety and effectiveness have been raised.