October 11, 2019

Zimmer GmbH
Danielle Madureira
Senior Specialist, Regulatory Affairs
Sulzerallee 8
CH-8404 Winterthur
Switzerland

Re: K192312
Trade/Device Name: Zimmer Natural Nail System Cephalomedullary Nails
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: August 21, 2019
Received: August 26, 2019

Dear Danielle Madureira:

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
Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Stereotaxic, Trauma
and Restorative Devices
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)*

K192312

Device Name
ZIMMER® NATURAL NAIL® SYSTEM CEPHALOMEDULLARY NAIL

Indications for Use *(Describe)*

The Zimmer Natural Nail System is intended for temporary fracture fixation and stabilization of the bone. Indications for the Cephalomedullary nails include:

- Compound and simple shaft fractures
- Proximal, metaphyseal and distal shaft fractures
- Segmental fractures
- Comminuted fractures
- Fractures involving osteopenic and osteoporotic bone
- Pathological fractures
- Fractures with bone loss
- Pseudoarthrosis, non-union, mal-union and delayed union
- Periprosthetic fractures
- Surgically created defects such as osteotomies
- Intertrochanteric and subtrochanteric fractures

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.

K192312

510(k) Summary

Sponsor:	Zimmer GmbH Sulzerallee 8, P.O. Box 8404 Winterthur, Switzerland
Contact Person:	Danielle Jannuzzi Madureira Senior Specialist, Regulatory Affairs Telephone: +41 58 854 82 60 Fax: +41 52 244 86 58
Date:	October 21, 2019
Trade Name:	ZIMMER® NATURAL NAIL® SYSTEM CEPHALOMEDULLARY NAIL
Classification Product Code :	HSB - Intramedullary Fixation Rod
Device Classification Name:	Rod, fixation, intramedullary and accessories
Regulation Number / Description:	21 CFR § 888.3020 Intramedullary fixation rod
Predicate Device:	Zimmer Natural Nail System Cephalomedullary Nails, manufactured by Zimmer GmbH, K091566, cleared October 2009 and its line extension Zimmer Natural Nail System Cephalomedullary Femoral Nails – Asia Short, manufactured by Zimmer GmbH, K120715, cleared October 2012
Device Description:	The Zimmer® Natural Nail® System Cephalomedullary Nails are temporary fixation intramedullary nails designed for fracture fixation and stabilization of the femur. They restore the shape of preinjured bone and are available in a variety of lengths and diameters to meet assorted anatomical needs. Nail caps are available to protect the nail threads from tissue ingrowth and extend the nail length if necessary. Each of the intramedullary nails is secured by a series of screws that pass through holes in the nail. A set screw (with a polyethylene peg) allows guided rotational stability of the lag screw. Nails, nail caps and screws are made from Tivanium Ti-6Al-4V Alloy. Set screws are made from Tivanium Ti-6Al-4V Alloy and Polyethylene (PE). Selected components of the Zimmer Natural Nail System are color coded to aid in identifying which components should be used together. The package label for each of the nails indicates which screw sizes should be used with that nail. A screw case that holds unused screws intended for resterilization is available and contains designated sections for each screw size. Each section contains the color name that matches the color/color name on the label of the appropriate screw size for that section. Refer to the color coding chart and/or surgical technique for more detailed instructions on the use of Zimmer Natural Nail System components.

Intended Use:	The Zimmer Natural Nail System is intended for temporary fracture fixation and stabilization of the bone. Indications for the Cephalomedullary nails include: • Compound and simple shaft fractures • Proximal, metaphyseal and distal shaft fractures • Segmental fractures • Comminuted fractures • Fractures involving osteopenic and osteoporotic bone • Pathological fractures • Fractures with bone loss • Pseudoarthrosis, non-union, mal-union and delayed union • Periprosthetic fractures • Surgically created defects such as osteotomies • Intertrochanteric and subtrochanteric fractures
Comparison to Predicate Device:	The intended use of the modified devices, as described in its labeling, has not changed as a result of the modifications proposed in the present submission. Zimmer GmbH is seeking clearance for certain system specific Class II instruments - these instruments that have previously considered Class I exempt and correction of classification to Class II is proposed within present submission.
Performance Data (Nonclinical and/or Clinical):	*Non-Clinical Performance and Conclusions:* Class II: Amendment of Design Controls with verification of mechanical integrity and resistance. *Clinical Performance and Conclusions:* Clinical data and conclusions were not needed for this device.
Conclusion:	The subject devices have the same intended use and similar indications for use as the predicate devices. The subject devices use the same operating principle, incorporate the same basic design and labeling and are manufactured and sterilized using the same materials and processes as the predicate devices. Except for the modifications described in this submission the subject devices are identical to the predicate devices, and the performance data and analyses demonstrate that: • any differences do not raise new questions of safety and effectiveness as established with performance testing; and • the subject devices are at least as safe and effective as the legally marketed predicate devices.