Zimmer GmbH
Tiana Steinhoff
Senior Specialist, Regulatory Affairs
Sulzerallee 8, P.O. Box
8404 WINTERTHUR, Switzerland

April 28, 2020

Re: K200814
Trade/Device Name: Affixus® Natural Nail® System Humeral Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: March 24, 2020
Received: March 30, 2020

Dear Tiana Steinhoff:

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: Michael Owens
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty 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)*

K200814

Device Name
AFFIXUS® NATURAL NAIL® SYSTEM HUMERAL NAIL

Indications for Use *(Describe)*

The AFFIXUS® Natural Nail® System Humeral nails are temporary fixation intramedullary nails designed for fixation and stabilization of fractures or osteotomies of the humerus. 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.

The AFFIXUS Humeral Nails are indicated for use in a variety of fractures, such as:
- Proximal fractures (proximal short and long nails only)
- Diaphyseal fractures (proximal long, antegrade/retrograde nails)
- Open and closed fractures
- Comminuted fractures
- Nonunions and malunions
- Pathologic 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

ZIMMER BIOMET

510(k) Summary

Sponsor:	Zimmer GmbH Sulzerallee 8, P.O. Box 8404 Winterthur, Switzerland
Contact Person:	Tiana Steinhoff Senior Specialist, Regulatory Affairs Telephone: +41 58 854 82 96 Fax: +41 52 244 86 58
Date:	March 24th 2020
Trade Name:	Affixus® Natural Nail® System Humeral Nail
Classification Product Code :	HSB - Intramedullary Fixation Rod
Device Classification Name:	Rod, fixation, intramedullary and accessories
Regulation Number / Description:	21 CFR § 888.3020 number – Intramedullary fixation rod
Predicate Device:	Affixus® Natural Nail® System Humeral Nails manufactured by Zimmer GmbH, K181827 cleared on 14th December 2018
Reference Device	Zimmer® Natural Nail™ System Cephalomedullary Nails manufactured by Zimmer GmbH, K091566 cleared on 28th October 2009
Device Description:	The Affixus Natural Nail System Humeral nails are temporary fixation intramedullary nails designed for fixation and stabilization of fractures or osteotomies of the humerus. 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. Nails and nail caps are made from Tivanium® Ti-6Al-4V alloy. Screws are also made from Tivanium alloy. Package labels indicate the material of each component. Selected components of the Affixus Natural Nail System are colour coded to aid in identifying which components should be used together. Refer to the colour coding chart and/or surgical technique for more detailed instructions on the use of Affixus Natural Nail System components.
Intended Use	The Affixus® Natural Nail® System Humeral nails are temporary fixation intramedullary nails designed for fixation and stabilization of fractures or osteotomies of the humerus. 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

ZIMMER BIOMET

	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. The Affixus® Humeral Nails are indicated for use in a variety of fractures, such as, proximal fractures (proximal short and long nails only), diaphyseal fractures (proximal long, antegrade/retrograde nails), open and closed fractures, comminuted fractures, nonunions and malunions and pathologic 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. Design, materials and performance characteristics remain unchanged.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: Non-clinical performance and conclusions were not needed for this device. Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device
Conclusion:	The subject devices have the same intended use and same 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.