December 14, 2018

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

Re: K181827
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: November 8, 2018
Received: November 13, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vesa Vuniqi -S

Digitally signed by Vesa Vuniqi -S
Date: 2018.12.14 16:07:07 -05'00'

For: Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*

K181827

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.

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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:	June 29th, 2018
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:	Versanail® Nailing System, manufactured by Biomet Trauma Inc, *K033878* (Ace® Antegrade Retrograde Humeral Nail System, primary predicate) and *K033806* (Ace® Proximal Humeral Nail System) both cleared in 20 February 2004 and M/DN® Intramedullary Fixation System, manufactured by Zimmer Inc, *K142281* cleared 22 October 2014, *K965098* cleared in 28 February 1997.
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 color coded to aid in identifying which components should be used together. Refer to the color coding chart and/or surgical technique for more detailed instructions on the use of Affixus Natural Nail System components.
Intended Use and Indications for 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 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 Affixus® Natural Nail® System Humeral nails, screws, washers, nail caps covered by this submission are similar in intended use, design, materials, and performance characteristics to the predicate devices. The Differences in the technological characteristics between the primary predicate VersaNail and the subject device Affixus® Natural Nail (ANN) Humeral Nail are as follows:

- Proximal and distal locking screws diameter: subject device screws have smaller diameters than the predicate device
- Nail-screw configuration, including screw orientation: subject device has a different in range of the screw orientation (screw hole pattern) to the predicate device. Adequate primary stability within all 3 planes can be achieved with both respective nails based on the screw insertion options provided.
- Axial compression: subject device provides an axial compression mechanism in the long device variants (Proximal Long and AR), allowing a controlled axial compression. The AR variant of the predicate device does not include such an option, and axial compression must be performed free-hand. However, the free-hand option can also be applied with the subject device.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Results of non-clinical performance testing and analyses demonstrate that the Affixus Humeral Nails is as safe, as effective, and performs as well as or better than the legally market devices predicate. Performance analyses included:

1. Bioburden study and technical review of Affixus Humeral Nails New Product Introduction (NPI) project
2. Biocompatibility of Affixus® Natural Nail® (ANN) Humeral Nail
3. Measurement of Torsional Stiffness of Affixus Humeral Nails
4. Static four point bend test of Affixus Humeral Nails
5. Fatigue strength evaluation of the Affixus blunt tip screw and cortical screws using a three-point bending test setup
6. Self-tapping performance of Affixus proximal blunt tip screw 4 mm and cortical bone screw 4 mm
7. Four point bending fatigue properties of Affixus Humeral Nails
8. Determining the driving torque of Affixus Proximal blunt tip screw 4 mm and cortical bone screw 4 mm

9. Determining the axial pull-out strength of Affixus Proximal blunt tip screw 4 mm and cortical bone screw 4 mm

10. Torsional properties of the Affixus Proximal blunt tip screw 4 mm and cortical bone screw 4 mm

11. Bending fatigue strength and CoreLock Evaluation of the proximal segment (including the mid-shaft segment) of the Affixus Humeral Nail system

12. Axial push-out strength evaluation of the Affixus Humeral Nail locking screw fixed by the CoreLock mechanis

13. Cleaning, autoclave, targeting functionality and impact testing of the Affixus Humerus targeting guides

The tests were performed according to the applicable Standards: ISO 11137-2, ISO 10993-1, ASTM 136-13, ASTM F543-17, ASTM F1264-16, and ISO 6475.

Clinical Performance and Conclusions:

The results of non-clinical data demonstrate that the subject device is substantially equivalent with the predicate devices.