August 9, 2023

Zimmer Switzerland Manufacturing GmbH
Melanie Mitrov
Regulatory Affairs Sr Specialist
Sulzerallee 8
Winterthur, Zürich 8404
Switzerland

Re: K231114
Trade/Device Name: Zimmer® Natural Nail® System Cephalomedullary Nails; Affixus® Natural Nail® Humeral Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: June 12, 2023
Received: June 12, 2023

Dear Melanie Mitrov:

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,

Farzana Sharmin -S

Digitally signed by Farzana Sharmin -S
Date: 2023.08.09 14:27:40 -04'00'

Farzana Sharmin, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231114

Device Name
ZIMMER® NATURAL NAIL® SYSTEM CEPHALOMEDULLARY NAILS

Indications for Use *(Describe)*
The Zimmer Natural Nail System Cephalomedullary Nails (ZNN™ CMN) are intramedullary nails intended for temporary internal fixation and stabilization of femoral fractures or osteotomies. Indications for the Zimmer Natural Nail System Cephalomedullary Nails (ZNN™ CMN) 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.

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
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
AFFIXUS® NATURAL NAIL® HUMERAL NAIL SYSTEM

Indications for Use *(Describe)*
The Affixus Natural Nail Humeral Nail System nails are intramedullary nails intended for temporary internal fixation and stabilization of humeral fractures or osteotomies.
The Affixus Natural Nail Humeral Nail System is indicated for use in a variety of fractures, such as:
• Proximal fractures (proximal short and long nails only).
• Diaphyseal fractures (proximal long nails and antegrade/retrograde nails only).
• 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.

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510 (k) Summary

Sponsor:	Zimmer Switzerland Manufacturing GmbH Sulzerallee 8, P.O. Box 8404 Winterthur, Switzerland
Contact Person:	Melanie Mitrov Regulatory Affairs Sr. Specialist Telephone: +41 79153 08 53 Fax: +41 52 244 86 58
Date:	August 7th, 2023
Trade Name:	Zimmer® Natural Nail® System Cephalomedullary Nails; Affixus® Natural Nail® Humeral Nail System.
Classification Product Code :	HSB-Rod, Fixation, Intramedullary And Accessories (21 CFR §888.3020)
Device Classification Name:	Intramedullary Fixation Rod
Regulation Number / Description:	21 CFR § 888.3020- Intramedullary Fixation Rod
Predicate Device:	Zimmer® Natural Nail™ System Cephalomedullary Nails, manufactured by Zimmer GmbH, K091566, cleared on October 28, 2009 Affixus® Natural Nail® System Humeral Nail, manufactured by Zimmer GmbH, K181827, cleared on December 14, 2018
Device Description:	The **Zimmer Natural Nail System Cephalomedullary Nails** are intramedullary nails designed to 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. 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.

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The **Affixus Natural Nail Humeral Nail System** consists of temporary fixation intramedullary nails designed for fixation and stabilization of fractures or osteotomies of the humerus. The nails restore the shape of preinjured bone and they 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 Ante/Retrograde Humerus Nails, Ante/Retrograde Humeral Nail Caps, Proximal Humerus Nail Caps, Washers, Cortical Bone Screws, and Blunt Tip Screws are made of Titanium alloy [Protasul®-64WF (Ti-6Al-4V) ISO 5832-3/ASTM F136] and Proximal Humerus Nails are made of Titanium alloy [Protasul-64WF (Ti-6Al-4V) ISO 5832-3/ASTM F136] and C.P Titanium [Protasul®-Ti ISO 5832-2/ASTM F67].

Package labels indicate the material of each component. Selected components of the Affixus Natural Nail Humeral Nail System instruments are color coded to aid in identifying which components should be used together. Refer to the surgical techniques for more detailed instructions on the use of Affixus Natural Nail Humeral Nail System components.

The purpose of this traditional bundled 510(k) is to update the Instructions for Use (IFU) and labels of the Zimmer® Natural Nail® System Cephalomedullary Nails and Affixus® Natural Nail® Humeral Nail System to include MR Conditional labeling. Additionally, to harmonize the content format of the IFU, some chapters of the IFUs are reorganized.

Indications for use :

The **Zimmer Natural Nail System Cephalomedullary Nails (ZNN™ CMN)** are intramedullary nails intended for temporary internal fixation and stabilization of femoral fractures or osteotomies. Indications for the Zimmer Natural Nail System Cephalomedullary Nails (ZNN™ CMN) 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.

The **Affixus Natural Nail Humeral Nail System** nails are

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	intramedullary nails intended for temporary internal fixation and stabilization of humeral fractures or osteotomies. The Affixus Natural Nail Humeral Nail System is indicated for use in a variety of fractures, such as: • Proximal fractures (proximal short and long nails only). • Diaphyseal fractures (proximal long nails and antegrade/retrograde nails only). • Open and closed fractures. • Comminuted fractures. • Nonunions and malunions. • Pathologic fractures.
Comparison to Predicate Device:	The subject devices have identical intended use and are substantially equivalent to the legally marketed predicated devices.
Summary of Technological Characteristics:	The rationale for substantial equivalence is based on consideration of the following characteristics: • **Intended Use:** Identical to predicates • **Indications for Use:** Identical to predicates • **Device Description:** Identical to the predicates • **Materials:** Identical to predicates • **Design Features**: Identical to predicates • **Lengths and diameters:** Identical to predicates • **Sterilization:** Identical to predicates
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: Evaluation of MR compatibility to support MR Conditional labeling • ASTM F2503-20 (Labeling) • ASTM F2119-07R13 (Artifact) • ASTM F213-17 (Torque) • ASTM F2052-21 (Displacement Force) • ASTM F2182-19E02 (RF-heating) – Preliminary Phantom Eval. Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device.
Conclusion:	The subject devices have identical intended use and identical 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 to the labeling 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 different questions of safety and effectiveness as established with performance testing; and • the subject devices are as safe and effective as the legally marketed predicate devices.