December 12, 2025

Zimmer Switzerland Manufacturing GmbH
Melanie Mitrov
Regulatory Affairs Sr. Specialist II
Sulzerallee 8
Winterthur, ZH 8404
Switzerland

Re: K253749
Trade/Device Name: Affixus® Natural Nail® Proximal Humeral System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: November 25, 2025
Received: November 25, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Farzana Sharmin, PhD
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253749

Please provide the device trade name(s).

Affixus® Natural Nail® Proximal Humeral System

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #:

510(k) Summary

Prepared on: 2025-12-12

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Zimmer Switzerland Manufacturing GmbH
Applicant Address	Sulzerallee 8, 8404 Winterthur, Switzerland Winterthur ZH 8404 Switzerland
Applicant Contact Telephone	+41791530853
Applicant Contact	Ms. Melanie Mitrov
Applicant Contact Email	melanie.mitrov@zimmerbiomet.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Affixus® Natural Nail® Proximal Humeral System
Common Name	Intramedullary fixation rod
Classification Name	Rod, Fixation, Intramedullary And Accessories
Regulation Number	888.3020
Product Code(s)	HSB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K231114	Affixus® Natural Nail® Humeral Nail System	HSB
K200814	Affixus® Natural Nail® System Humeral Nail	HSB
K181827	Affixus® Natural Nail® System Humeral Nail	HSB
K033806	ACE PROXIMAL HUMERAL NAIL SYSTEM	HSB
K033878	ACE ANTEGRADE RETROGRADE HUMERAL NAIL SYSTEM	HSB

Device Description Summary

21 CFR 807.92(a)(4)

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 patient needs. The humeral nails are used together with Bone Screws, Washers, and Nail Caps. 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 locking mechanism feature (CoreLock™) in the proximal segment of the Proximal Humeral Nails provides the option to lock 4.0 mm diameter Blunt Tip Screws within the nail. CoreLock™ secures the screws against medial or lateral migration. The current design locks on the outer thread diameter of the screw, relying on friction.
The 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].
The reason for this submission is to introduce a design change of the CoreLock™ locking system in the Affixus® Natural Nail® Humeral Nails by replacing the teeth profile with a multiple thread pitch. The new design preserves the friction fit mechanism and adds a form-fit

interaction for enhanced locking performance.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications between the predicate and the subject device are the same.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device, Affixus® Natural Nail® Humeral Nail System, maintains the same fundamental technological characteristics, intended use, and indications for use as the predicate device (Affixus® Natural Nail® Humeral Nail System, K231114). The only modification is an update to the CoreLock™ interface, changing the engagement mechanism from a teeth profile in the predicate device to a multiple thread pitch design in the subject device. This Special 510(k) is being submitted solely to address this minor design difference. The updated CoreLock™ interface preserves the same friction-fit principle as the predicate and does not introduce different risks, alter device function, or change clinical use. Verification and performance testing, including repeat biomechanical CoreLock™ Strength Evaluations conducted using well-established, standardized methods, demonstrate that the modified interface meets all performance requirements and does not raise different questions of safety or effectiveness. Overall, the data provided support that the subject device is at least as safe and effective as the legally marketed predicate device and is substantially equivalent in technological characteristics and performance.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-Clinical Performance: Verification testing was performed to assess the updated CoreLock™ interface, including mechanical integrity and engagement strength. All testing met predetermined acceptance criteria, were compared to the predicate, and confirmed that the design modification does not raise different questions of safety or effectiveness.
Clinical Performance: Clinical data were not required. Non-clinical testing was sufficient to support substantial equivalence.

Conclusion: The subject device has the same intended use and same indications for use as the predicate device. The subject device uses 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 device.
Except for the modifications to the CoreLock™ interface described in this submission the subject device is identical to the predicate device, 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 at least as safe and effective as the legally marketed predicate device.