February 12, 2025

Zimmer Inc.
Akash Savalia
Regulatory Affairs Sr. Specialist
1800 W Center Street
Warsaw, Indiana 46580

Re: K243907
Trade/Device Name: Affixus Tibial Nailing System - 4mm screws
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, HWC
Dated: December 19, 2024
Received: December 19, 2024

Dear Akash Savalia:

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

Digitally signed by Farzana Sharmin -S
Date: 2025.02.12 12:56:40 -05'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243907

Device Name

Affixus Tibial Nailing System - 4mm screws

Indications for Use *(Describe)*

The Affixus® Tibial Nailing System is indicated for temporary stabilization and fixation of tibial fractures and osteotomies including proximal, metaphyseal, and distal shaft fractures, closed fractures, open fractures, pathologic fractures, non-unions, malunions and deformity corrections.

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."

510(k) #:

510(k) Summary

Prepared on: 2025-02-11

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Zimmer Inc.
Applicant Address	1800 W Center Street Warsaw IN 46580 United States
Applicant Contact Telephone	1-978-908-0222
Applicant Contact	Mr. Akash Savalia
Applicant Contact Email	akash.savalia@zimmerbiomet.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Affixus Tibial Nailing System - 4mm screws
Common Name	Rod, Fixation, Intramedullary And Accessories
Classification Name	Intramedullary fixation rod
Regulation Number	888.3020
Product Code(s)	HSB, HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K241651	Affixus Tibial and Antegrade Femoral Nailing System	HSB
K142281	ZIMMER M/DN INTRAMEDULLARY FIXATION SYSTEM	HSB
K082770	ZIMMER NATURAL NAIL SYSTEM TIBIAL NAIL	HSB
K063570	BIOMET TIBIAL LOCKING NAIL SYSTEM	HSB

Device Description Summary

21 CFR 807.92(a)(4)

The Affixus Tibial Nailing System is a long bone nailing system that offer implants designed to treat a range of tibial fractures from simple to complex, with versatile locking options. They restore the shape of preinjured bone and are available in a variety of lengths and diameters to meet assorted anatomical needs. Screws and End Caps are included in the system. All implants are made of Ti-6Al-4V. The Affixus platform of instrumentation is designed to provide options and flexibility for many intraoperative approaches while maintaining ease of use and commonality.
This submission introduces 4mm Cortical Bone Screws. These screws are also made of Ti-6AL-4V and feature a double-lead thread design with a self-tapping tip. Screw options include
Ø4mm: 20mm - 60mm, increments of 2 mm
60mm - 90mm, increments of 5mm
Note: 4mm Screws are inserted through distal locking holes of 8mm Tibia nails only.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Affixus® Tibial Nailing System is indicated for temporary stabilization and fixation of tibial fractures and osteotomies including

proximal, metaphyseal, and distal shaft fractures, closed fractures, open fractures, pathologic fractures, non-unions, malunions and deformity corrections.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use for the subject device are identical to the primary predicate Affixus Tibial Nailing System.

Technological Comparison

21 CFR 807.92(a)(6)

The proposed device has similar technological characteristics as the primary predicate system.
The following items are identical to the Affixus Tibial system cleared in K241651.
-Component Materials, raw and contact
-MRI conditional Status and MRI language
-Sterilization methods and validations
-Packaging materials, methods and validations
-Shelf life validations
-Biocompatibility

The rationale for substantial equivalence is based on consideration of the following characteristics:

- Materials: Identical to primary predicate device implants
- Design Features: Similar to predicate device
- Packaging: Similar to predicate device
- Sterilization: Similar to primary predicate device

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-Clinical Tests:
- Construct Bending Fatigue Strength
- Bone Screw Bending Strength per ASTM F1264 Annex 4
- Screw Maximum Torque to Failure and Breaking Angle per ASTM F543 Annex 1
- Screw Insertion/ Removal Torque per ASTM F543 Annex 2
- Screw Pullout Strength per ASTM F543 Annex 3
- Screw Self Tapping Performance per ASTM F543 Annex 4
- MR Compatibility Evaluation per ASTM F2182, ASTM F2052, F2119, ASTM 2213

The proposed device has a similar intended use as the predicates and similar technological characteristics. The information provided herein demonstrates that:
- different technological characteristics of the proposed device do not raise new questions of safety and effectiveness; and
- the proposed device is at least as safe and effective as the legally marketed predicate device.