March 12, 2026

Akash Savalia
Regulatory Affairs Sr. Specialist
1800 W Center St.
Warsaw, Indiana 46835

Re: K253566
Trade/Device Name: Affixus Retrograde Femoral Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: February 9, 2026
Received: February 9, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

Joseph P. Russell -S

for: 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.	K253566

Please provide the device trade name(s).

Affixus Retrograde Femoral Nailing System

Please provide your Indications for Use below.

The Affixus Retrograde Femoral Nailing System is indicated for:
- Compound and simple shaft fractures
- Proximal, metaphyseal and distal shaft fractures
- Segmental fractures
- Closed supracondylar fractures
- Severely comminuted supracondylar fractures with articular involvement
- Fractures involving femoral condyles
- Comminuted fractures
- Fractures involving osteopenic and osteoporotic bone
- Pathological fractures
- Fractures with bone loss
- Pseudoarthrosis, non union, and mal union
- Periprosthetic fractures
- Poly trauma patients

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

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K253566

510(k) Summary

Prepared on: 3/11/2026

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Zimmer Inc.
Applicant Address	1800 W Center St. Warsaw IN 46835 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 Retrograde Femoral Nailing System
Common Name	Rod, Fixation, Intramedullary and Accessories
Classification Name	Intramedullary fixation rod
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
K072161	Biomet Femoral Locking Nail System	HSB
K101622	Zimmer Natural Nail System Retrograde Femoral Nails	HSB
K241651	Affixus Tibial and Antegrade Femoral Nailing System	HSB

Device Description Summary

21 CFR 807.92(a)(4)

The Affixus Retrograde Femoral Nailing System is part of the Affixus long bone nailing platform, designed for the treatment of a wide range of femoral fractures, from simple to complex. The system provides multiple locking options to support fracture stability and healing. All nails are made of type II anodized 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.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Affixus Retrograde Femoral Nailing System is indicated for:

- Compound and simple shaft fractures
- Proximal, metaphyseal and distal shaft fractures
- Segmental fractures
- Closed supracondylar fractures
- Severely comminuted supracondylar fractures with articular involvement
- Fractures involving femoral condyles
- Comminuted fractures
- Fractures involving osteopenic and osteoporotic bone
- Pathological fractures
- Fractures with bone loss

- Pseudoarthrosis, non union, and mal union
- Periprosthetic fractures
- Poly trauma patients

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use are similar between the predicate and subject device. As demonstrated by evidence presented in this submission, including non-clinical tests, the subject device is safe and effective for the stated indications for use despite any differences to the predicates.

Technological Comparison 21 CFR 807.92(a)(6)

The proposed device has similar technological characteristics as the primary predicate system. 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 devices. Minor differences in features, including implant geometry do not affect safety or effectiveness as supported by non-clinical tests included in this submission.
- Packaging: Similar to predicate devices
- Sterilization: Similar to primary predicate device

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-Clinical Tests:
- Engineering Analysis to Evaluate Nail Static Strength/Stiffness, Static Torsional Stiffness, and Bending Fatigue Strength
- 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:

- any differences do not raise different questions of safety and effectiveness; and
- the proposed device is at least as safe and effective as the legally marketed predicate devices.