March 18, 2026

Fusion Orthopedics USA, LLC
Catalina Pardo
Quality Engineer
6859 E Rembrandt Ave
Suite 122
Mesa, Arizona 85212

Re: K252961
Trade/Device Name: Fusion FibFix Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: February 19, 2026
Received: February 19, 2026

Dear Catalina Pardo:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

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.	K252961

Please provide the device trade name(s).

Fusion FibFix Nail

Please provide your Indications for Use below.

The Fusion FibFix Nail is intended for use in the fixation of fibula fractures and osteotomies.

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

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

March 17, 2026
Fusion FibFix Nail
Fusion Orthopedics USA, LLC
Traditional 510(k)

510(k) Summary: Fusion FibFix Nail

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	March 17th, 2026
Submitted By	Fusion Orthopedics USA, LLC 6859 E. Rembrandt Ave., Suite 122 Mesa, AZ 85212 800-403-6876
Primary Contact	Catalina Rincon 6859 E. Rembrandt Ave., Suite 122 Mesa, AZ 85212 Telephone: 928-261-5033 e-mail: catalina@fusionorthopedics.com
Trade Name	Fusion FibFix Nail
Common Name	Rod, Fixation, Intramedullary and Accessories
Class	II
Product Code	HSB
Regulation	21 CFR Section 888.3020, Intramedullary Fixation Rod
Device Panel	Orthopedic
Predicate Devices	**Primary Predicate:** Conventus Flower: Flex-Thread™ Distal Fibula Intramedullary Nail System (K212030) **Additional Predicate:** Acumed LLC: Small Bone Locking Rod System II (K031438)
Reference Devices	Fusion Orthopedics USA, LLC: Small Bone Plating System (K211843)
Device Description	The Fusion FibFix Nail consists of a titanium alloy (Ti6Al4V ELI (ASTM F136)) intramedullary fibula nail and threaded bone fixation fasteners for fixation of the ankle following trauma and osteotomy. The system includes corresponding instrumentation to support both insertion and removal. The Fusion FibFix Nail system includes intramedullary fibula nails, screws and end caps. Fibula nails are offered in 3.7mm, 4.7mm and 5.7mm diameters with lengths ranging from 130mm to 270mm. The included screws are offered in 2.7mm with lengths ranging from 10mm to 22mm. When clinically indicated, the system may be used in conjunction with adjunctive rigid or flexible syndesmotic fixation. Flexible syndesmotic fixation is provided by the Bolo Button System (K242091), and rigid fixation may be provided with 3.5mm and 4.0mm screws cleared under by the PolyLock Plating System (K211843). All implants are intended for single use only. Instruments designed for bone removal are intended for single use only, such as: Drill bits, reamers, k-wires, percutaneous screw targeting system and guide wires.
Indications for Use	The Fusion FibFix Nail is intended for use in the fixation of fibula fractures and osteotomies.

Materials	Titanium Alloy Ti6Al4V ELI (ASTM F136)
Comparison of Technological Characteristics	The Fusion FibFix Nail and the predicate device implants are manufactured from titanium alloy (ASTM F136) and are compatible with similar sized nails, have similar widths, thickness, lengths, and designs/shapes. Systems are equivalent in their features and in intended use.
Non-clinical Test Summary	Validations were performed on the cleaning, packaging and sterilization of the implants and associated surgical instruments. Engineering rational along with static and dynamic testing was performed to show substantial performance equivalence. The results of the testing demonstrate that the device is substantially equivalent to the predicate device identified above.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non- clinical and Clinical	Fusion Orthopedics USA, LLC considers the Fusion FibFix Nail to be equivalent to the predicate device listed above. This conclusion is based upon the subject devices' similarities in principles of operation, technology, materials, and indications for use.