March 5, 2026

Arthrex Inc.
Jessica Kim
Senior Regulatory Affairs Specialist
1370 Creekside Blvd.
Naples, Florida 34108

Re: K252196
Trade/Device Name: Arthrex FibuLock Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, HTN, HWC
Dated: February 3, 2026
Received: February 3, 2026

Dear Jessica Kim:

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), 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 Medical Device File (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,

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.	K252196

Please provide the device trade name(s).

Arthrex FibuLock Nail System

Please provide your Indications for Use below.

The Arthrex FibuLock Nail System is intended for use in the fixation of fibula fractures and osteotomies.

The Buttress Plate is intended for use with the FibuLock PRO Nail and Arthrex TightRope Syndesmosis Devices to support additional stabilization for fibula fractures. The Buttress Plate is designed for use with the FibuLock PRO Nail and TightRope Syndesmosis devices and may not be used as a stand-alone device.

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) Summary

Date Prepared	03/05/2026
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Jessica Kim Title: Senior Regulatory Affairs Specialist Phone: 1-239-643-5553, ext. 73892 Email: Jessica.Kim@Arthrex.com
Trade Name	Arthrex FibuLock Nail System
Common Name	Intramedullary Fixation Rod (rod, fixation, intramedullary and accessories)
Product Code	HSB
Classification Name	21 CFR 888.3020, Intramedullary Fixation Rod
Regulatory Class	II
Primary Predicate Device	K173656: Arthrex FibuLock Nail
Additional Predicate Devices	K160069: Sonoma Fibula Repair System
Reference Devices	K222267: Arthrex 2.4 mm Volar Distal Radius Plate System K230257: Arthrex Intramedullary Nails K221031: Arthrex DualCompression Hindfoot Nail System K203294: Arthrex Pilon Fusion System K201522: Arthrex Syndesmosis TightRope XP Buttress Plate Implant System
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex FibuLock Nail System.
Device Description	The Arthrex FibuLock Nail System is comprised of FibuLock Nails, Headless Cortical Screws, End Caps, and Buttress Plates. The FibuLock Nail is manufactured from 316L stainless steel conforming to ASTM F138. The FibuLock Nails have a proximal diameter of 3.0 mm to 3.8 mm, a 6-degree lateral bend, and are available in left and right configurations. The FibuLock Nail utilizes fixation grippers (“talons”), at the proximal end of the nail to allow for proximal fixation without the use of screws at. The talon supplements the traditional three-point fixation with an expanding gripper to provide proximal fixation of the fracture and prevent nail migration.

	The Headless Cortical Screws are used with the Arthrex FibuLock Nail System for the fixation of fibula fractures and osteotomies. The headless cortical screws are manufactured from 316L stainless steel conforming to ASTM F138. The Headless Cortical Screws are solid, fully threaded, non-locking screws that range from 2.7 mm to 3.8 mm in diameter and have lengths from 10 mm to 65 mm. The End Caps were previously cleared under K160069. The End Caps are manufactured from 316L stainless steel conforming to ASTM F138 and designed to be inserted into the FibuLock Nail to close off the end of the implant. The end caps range from 7.62 mm to 13.94 mm in length and are available in 0 mm, 3 mm, and 5 mm configurations for different nail countersinking depths. The Buttress Plate is an adjunct device designed for use with the Arthrex FibuLock Nail System. It is not intended for stand-alone use. The Buttress Plate is available in two configurations: a 2-hole and a 3-hole design. At the discretion of the surgeon, the Buttress Plate may be used to provide additional fixation at the level of the fracture. The Arthrex FibuLock Nail System is manufactured from stainless steel, conforming to ASTM F138. The Arthrex FibuLock Nail System is single-use and sold either non-sterile or sterile (Gamma). The Arthrex FibuLock Nail System can also be used with existing FDA cleared Arthrex 2.7 mm and 3.5 Bone Screws (K173656), Arthrex TightRope Syndesmosis Devices (K043248, K201522), and instrumentation required for the fixation of fibula fractures and osteotomies.
Indications for Use	The Arthrex FibuLock Nail System is intended for use in the fixation of fibula fractures and osteotomies. The Buttress Plate is intended for use with the FibuLock PRO Nail and Arthrex TightRope Syndesmosis Devices to support additional stabilization for fibula fractures. The Buttress Plate is designed for use with the FibuLock PRO Nail and TightRope

	Syndesmosis devices and may not be used as a stand-alone device.
Performance Data	Arthrex conducted Taper Bend, Torque and Compression, Static/Dynamic, Torsion, and Fatigue Bending testing on the FibuLock PRO Nails within the FibuLock Nail System, in accordance with ASTM F1264, *Standard Specification and Test Methods for Intramedullary Fixation Devices*. Additionally, for the minor design modification to the FDA cleared FibuLock Nail (K173656), Torque and Compression testing was conducted to evaluate the expansion performance of the proximal talon, also following ASTM F1264, *Standard Specification and Test Methods for Intramedullary Fixation Devices*. This minor modification was incorporated into the FibuLock PRO Nails. Arthrex conducted torsional strength testing, torque testing, driving torque testing, pull-out testing, axial pull-out analysis, and cyclic fatigue bending testing in accordance with ASTM F543, *Standard Specification and Test Methods for Metallic Medical Bone Screws* and the FDA's guidance document, *Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway*, issued on December 11th, 2020 on the Headless Cortical Screws within the FibuLock Nail System. Cyclic and Shear Loading Testing was conducted to demonstrate that the Buttress Plates within the FibuLock Nail System performs statistically equivalent to the predicate device cleared under K201522. <u>Packaging for Sterile Devices:</u> • FibuLock PRO Nail: The double PETG Blister with Tyvek Lid packaging configuration FDA cleared in cleared in reference devices: K230257 (Arthrex Intramedullary Nails), and K221031 (Arthrex DualCompression Hindfoot Nail System). • End Caps: The sterile packaging configuration cleared in the reference devices: K230257 (Arthrex Intramedullary Nails), and K221031 (Arthrex DualCompression Hindfoot Nail System).

	• Headless Cortical Screws: The sterile packaging configuration is equivalent to the additional the cleared reference devices: K230257 (Arthrex Intramedullary Nails), and K221031 (Arthrex DualCompression Hindfoot Nail System). • Buttress Plates: The sterile packaging configuration of Double Poly / Tyvek Pouch is equivalent to primary predicate device cleared in K173656, Arthrex FibuLock Nail, and reference predicate devices cleared in K221031 (Arthrex DualCompression Hindfoot Nail System), K203294 (Arthrex Pilon Fusion System), and K201522 (Arthrex Syndesmosis TightRope XP Butress Plate Implant System). <u>Packaging for Non-Sterile Devices:</u> • End Caps: The non-sterile packaging configuration of Polyethylene Pouch is equivalent to reference device cleared in Arthrex 2.4 mm Volar Distal Radius Plate System (K222267). • Headless Cortical Screws: The packaging configuration non-sterile packaging is equivalent to the reference device cleared in Arthrex 2.4 mm Volar Distal Radius Plate System (K222267). • Buttress Plates: The non-sterile packaging configuration of Polyethylene Pouch is equivalent to reference device cleared in Arthrex 2.4 mm Volar Distal Radius Plate System (K222267). <u>Shelf-Life:</u> • The non-sterile End Caps, Headless Cortical Screws, and Buttress Plates within the Arthrex FibuLock Nail System have an unlimited shelf-life. • The sterile FibuLock Nail, End Caps, Headless Cortical Screws, Buttress plates have a 5-year shelf life which is equivalent to the additional predicate device, K201522 (Arthrex Syndesmosis TightRope XP Buttress Plate Implant System), and reference devices: K230257 (Arthrex Intramedullary Nails), K221031 (Arthrex DualCompression Hindfoot Nail System), K203294 (Arthrex Pilon Fusion System), and

	K201522 (Arthrex Syndesmosis TightRope XP Butress Plate Implant System). MRI force, torque, and image artifact testing were conducted in accordance with FDA guidance *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*, ASTM F2052 *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*, ASTM F2119 *Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants*, ASTM F2182 *Standard Test Method for Measurement of Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging* and ASTM F2213 *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment*. Cytotoxicity, Sensitization, Irritation, Genotoxicity, Systemic Toxicity, Subchronic/Subacute Toxicity, Implantation and Material Characterization testing was conducted on the FibuLock Nail System in accordance with ISO 10993-1:2018. Bacterial Endotoxins Test (BET) was performed on the Arthrex devices utilizing the Kinetic Chromogenic Method in accordance with ANSI/AAMI ST72:2011/(R)2016, USP <161>, USP <85>, EP 2.6.14. The testing conducted demonstrates that the sterile devices meet pyrogen limit specifications. Assessment of the physical product attributes including product, design, size, and materials has determined that the Arthrex FibuLock Nail System does not introduce additional risks or concerns regarding sterilization and shelf-life.
Technological Comparison	The Arthrex FibuLock Nail System is substantially equivalent to the primary predicate device, Arthrex FibuLock Nail (K173656) and additional predicate device, Sonoma Fibula Repair System (K160069) in which the basic design features, FibuLock nail configuration, intended use, fundamental scientific technology, materials, and sterility (Gamma) are identical. The Arthrex FibuLock Nail System is manufactured from stainless steel conforming to ASTM F138 which is equivalent to the primary predicate, K173656 (Arthrex FibuLock Nail),

	and additional predicate devices: K160069 (Sonoma Fibula Repair System), and K201522 (Arthrex Syndesmosis TightRope XP Buttress Plate Implant System). The FibuLock PRO Nails within the Arthrex FibuLock Nail System will be offered in longer nail length than the primary predicate device, Arthrex FibuLock Nail (K173656) and additional predicate device, Sonoma Fibula Repair System (K160069). The End Caps within the Arthrex FibuLock Nail System will be offered in additional sizes of 3 mm and 5 mm than the predicate device, Sonoma Fibula Repair System (K160069) which is only offered in 0 mm (flush) configuration. The Headless Cortical within the Arthrex FibuLock Nail System will be offered in 2.7 mm to 3.8 mm in diameter and lengths from 10 mm to 65 mm than the predicate device, 2.7 mm and 3.5 mm Bones Screws cleared in K173656 (Arthrex FibuLock Nail). The Buttress Plates within the Arthrex FibuLock Nail System will be offered with 2-Hole or 3-Hole Buttress Plates than the predicate device cleared in K201522 (Arthrex Syndesmosis TightRope XP Buttress Plate Implant System) which is only offered with a 2-Hole Butress Plate configuration. The FibuLock Nail System has been evaluated for MR Conditional labeling, whereas the predicate devices cleared under K173656 (Arthrex FibuLock Nail) were not evaluated for MR Conditional Labeling. The Arthrex FibuLock Nail System is substantially equivalent to the primary predicate device, Arthrex FibuLock Nail (K173656), and additional predicate devices: Sonoma Fibula Repair System (K160069), and Arthrex Syndesmosis TightRope XP Buttress Plate Implant System (K201522), with minor modifications with no change to the intended use, design, or function. Any differences between the Arthrex FibuLock Nail System and the predicate devices are considered minor and do not raise different questions of safety or effectiveness.

Conclusion	The Arthrex FibuLock Nail System is substantially equivalent to the primary predicate device, Arthrex FibuLock Nail (K173656), and additional predicate devices: Sonoma Fibula Repair System (K160069), and Arthrex Syndesmosis TightRope XP Buttress Plate Implant System (K201522), in which the basic design features and intended use are the same. Any differences between the Arthrex FibuLock Nail System and the predicate devices are considered minor and do not raise different questions of safety or effectiveness. Based on the indications for use, technological characteristics, and the performance testing submitted, Arthrex Inc. has determined that the Arthrex FibuLock Nail System is substantially equivalent to the currently marketed predicate device.