January 21, 2026

Arthrex, Inc.
Stacy Valdez
Principal Regulatory Affairs Specialist
1370 Creekside Blvd.
Naples, Florida 34108

Re: K253713
Trade/Device Name: Arthrex Variable Angle (VA) Proximal Tibia Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS
Dated: November 24, 2025
Received: November 24, 2025

Dear Ms. Valdez:

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.
Assistant Director
DHT6C: Division of Resotrative, Reprair,
And Trauma 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.	K253713

Please provide the device trade name(s).

Arthrex Variable Angle (VA) Proximal Tibia Plating System

Please provide your Indications for Use below.

The Arthrex Lateral Proximal Tibia Plate is indicated for adult patients, as well as patients with osteopenic bone. It is indicated for fixation of fractures of the tibia.

The Arthrex Medial Proximal Tibia Plate is indicated for adult patients, as well as patients with osteopenic bone. It is indicated for fixation of fractures of the tibia.

The Arthrex Posteromedial Proximal Tibia Plates are intended to be used for internal bone fixation for bone fractures in the tibia.

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

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

510(k) Summary

Date Prepared	11/24/2025
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Stacy Valdez Title: Principal Regulatory Affairs Specialist Phone: 1-239-643-5553, ext. 72010 Email: Stacy.Valdez@Arthrex.com
Trade Name	Arthrex Variable Angle (VA) Proximal Tibia Plating System
Common Name	Plate, Fixation, Bone
Product Code	HRS
Classification Name	21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class	II
Primary Predicate Device	K210837, Smith and Nephew's EVOS Small Fragment Plating System
Additional Predicate Devices	K123241, Arthrex Fracture Plates K222244, Arthrex 3.5 mm Locking Compression Plates
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Variable Angle (VA) Proximal Tibia Plating System.
Device Description	The Arthrex Variable Angle (VA) Proximal Tibia Plating System is designed for repairing fractures of the tibia. The Arthrex Variable Angle (VA) Proximal Tibia Plating System consists of two Lateral Proximal Tibia Plate types (Standard and High), Posteromedial Proximal Tibia Plates, and Medial Proximal Tibia Plates. The Lateral Proximal Tibia Plates are anatomically contoured, available in left and right configurations, varying plate lengths of 78 mm to 239 mm. The primary difference between the Standard and High Lateral Proximal Tibia Plates is that the High Lateral Proximal Tibia Plate includes four additional 2.7 mm screw holes proximally. The Medial Proximal Tibia Plates are anatomically contoured, available in left and right configuration, and varying plate lengths of 94 mm to 202 mm. The Posteromedial Proximal Tibia Plates are anatomically contoured straight plates offered in varying plate lengths of 87 mm to 137 mm. The Lateral, Posteromedial, and Medial

	Proximal Tibia Plates within the Arthrex Variable Angle (VA) Proximal Tibia Plating System accept variable angle (VA) and nominal angle locking screws, KreuLock™ screws, cortical screws, as well as cancellous screws. Additionally, the Variable Angle (VA) Proximal Tibia Plates includes K-wire holes for temporary fixation and suture holes to assist in soft tissue management. The proposed plates are manufactured from titanium alloy (Ti-6AL-4V ELI) conforming to ASTM F136 (ISO 5832-3). The Variable Angle (VA) Proximal Tibia Plates are single use and sold either sterile (Gamma) or non-sterile. The Arthrex Variable Angle (VA) Proximal Tibia Plating System are compatible with the following Arthrex Screws: • 2.7 mm Cortical Screw and 2.7 mm VAL Screw (K220937) • 2.7 mm VAL KreuLock Screws (K242554) • 3.0 mm Low Profile VA Locking Screw (K213837) • 3.0 mm KreuLock™ Compression Screw, 3.0 Low Profile VA Locking Screw, Hybrid, 3.0 mm Hybrid KreuLock™ Compression Screw (K242554) • 3.5 mm Low Profile Screw (K203294, K150456, K143614, K123241, K111253, K103705) • 3.5 mm Low Profile Locking Screws (K150456, K143614, K111253, K103705) • 3.5 mm Variable Angle Locking (VAL) Screw, Reinforced, 3.5 mm Variable Angle Locking (VAL) KreuLock™ Screw, Reinforced, 3.5 VAL Screw, 3.5 mm VAL KreuLock Screws (K241592) • 4.0 mm Low Profile Screw, Cancellous (K150456, K143614, K111253, K103705)
Indications for Use	The Arthrex Lateral Proximal Tibia Plate is indicated for adult patients, as well as patients with osteopenic bone. It is indicated for fixation of fractures of the tibia. The Arthrex Medial Proximal Tibia Plate is indicated for adult patients, as well as patients with osteopenic bone. It is indicated for fixation of fractures of the tibia. The Arthrex Posteromedial Proximal Tibia Plates are intended to be used for internal bone fixation for bone fractures in the tibia.

Performance Data	Arthrex performed 4-point bend testing in accordance with ASTM F382-24 to demonstrate that the Lateral and Medial Proximal Tibia Plates are statistically equivalent in performance to the primary predicate device (K210837, Smith & Nephew EVOS Small Fragment Plating System) and the additional predicate device (K222244, Arthrex 3.5 mm Locking Compression Plates). Additionally, 4-point bend testing per ASTM F382-24 was conducted to support that the Posteromedial Proximal Tibia Plates are statistically equivalent to the additional predicate device (K123241, Arthrex Fracture Plates). Arthrex conducted packaging validation and 5-year accelerated aging shelf-life testing to demonstrate that the smaller and medium (127 mm to 208 mm length) packaging configurations are capable of maintaining and protecting the product and sterility of the device throughout the shipping and handling environment. The proposed packaging configurations met all the packaging testing acceptance criteria in accordance with ISO 11607 and applicable standards. 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*. 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 Variable Angle (VA) Proximal Tibia Plating System does not introduce additional risks or concerns regarding sterilization and shelf-life.
Technological Comparison	The main differences with the predicate devices are specified below: • The Lateral and Medial Proximal Tibia Plates within the Arthrex Variable Angle (VA) Proximal Tibia Plating System will be offered in wider and thicker plate shaft than the primary predicate device, Smith & Nephew EVOS Small Fragment Plating System (K210837). • The Posteromedial Proximal Tibia Plate within the Arthrex Variable Angle (VA) Proximal Tibia Plating System will be offered in thicker plate shaft than the reference predicate device, Arthrex 3.5 mm Locking Compression Plates (K222244).
Conclusion	The Arthrex Variable Angle (VA) Proximal Tibia Plating System is substantially equivalent to the predicate devices cleared under the primary predicate, Smith & Nephew EVOS Small Fragment Plating System (K210837) and additional predicate devices, Arthrex 3.5 mm Locking Compression Plates (K222244) and Arthrex Fracture Plates (K123241). Any differences between the Arthrex Variable Angle (VA) Proximal Tibia Plating System and the predicate devices are considered minor and do not raise different questions of safety and effectiveness. Based on the intended use (indications for use), technological characteristics, and the summary of data submitted, Arthrex Inc. has determined that the proposed device is substantially equivalent to the currently marketed predicate devices.