January 12, 2026

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

Re: K252807
Trade/Device Name: Arthrex Anatomic Lapidus Plates and I-Beam Lapidus Plates
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: December 15, 2025
Received: December 15, 2025

Dear Stacy 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,

Thomas Mcnamara -S

For: Christopher Ferreira, M.S.
Assistant Director
DHT6C: Division of Restorative,
Repair, 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.	K252807

Please provide the device trade name(s).

Arthrex Anatomic Lapidus Plates and I-Beam Lapidus Plates

Please provide your Indications for Use below.

The Anatomic Lapidus Plates and I-Beam Lapidus Plates are intended for use in stabilization of fresh fractures, revision procedures, osteotomies, joint fusion and reconstruction of small bones and bone fragments of the foot.

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	01/05/2026
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 Anatomic Lapidus Plates and I-Beam Lapidus Plates
Common Name	Plate, Fixation, Bone
Product Code	HRS, HWC
Classification Name	21 CFR 888.3030: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories 32 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Regulatory Class	II
Primary Predicate Device	K111253: Arthrex Distal Extremity Plate System
Additional Predicate Devices	K150456: Arthrex Plates, Screws, and Staples
Reference Devices	K242079: Arthrex Elbow Fracture Plating System 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 Anatomic Lapidus Plates and I-Beam Lapidus Plates.
Device Description	The Arthrex Anatomic Lapidus Plates and I-Beam Lapidus Plates consists of a series of plates of varying sizes, orientations, and lengths. The proposed plates are available in small, medium, and long, and left and right configurations. The proposed plates (I-Beam Lapidus Plates only) include an internal beam. Each plate provides locking screw fixation. The proposed plates are manufactured from titanium alloy conforming to ASTM F136. The proposed plates are sold sterile (gamma) and are single-use. The proposed Anatomic Lapidus Plates are sold as standalone, whereas the I-Beam Lapidus Plates are packaged as a kit with instrumentation.
Indications for Use	The Anatomic Lapidus Plates and I-Beam Lapidus Plates are intended for use in stabilization of fresh fractures, revision procedures, osteotomies, joint fusion and reconstruction of small bones and bone fragments of the foot.

Performance Data	To demonstrate product performance, Arthrex has conducted static and dynamic 4-point bend testing on the proposed Arthrex Anatomic Lapidus Plates and I-Beam Lapidus Plates comparing the results to the primary predicate device Arthrex Distal Extremity Plate System (K111253) in accordance with ASTM F382-17 *Standard Specification and Test Method for Metallic Medical Bone Plates,* Annex A1. Arthrex conducted packaging validation and 5-year real-time aging shelf-life testing to demonstrate that the 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 conformance to 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*. Arthrex devices are tested for endotoxins and produced passing results in accordance with AAMI ST72 – Limulus Amoebocyte Lysate (LAL) testing conducted per the kinetic turbidimetric method. All samples were tested in accordance with and met the requirements (<20 EU/device) of USP <85> Bacterial Endotoxins Test, and USP <161>, Transfusion and Infusions Assemblies and Similar Medical Devices. 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 Anatomic Lapidus Plates and I-Beam Lapidus Plates do not introduce additional risks or concerns regarding sterilization and shelf-life.
Technological Comparison	The Arthrex Anatomic Lapidus Plates and I-Beam Lapidus Plates are substantially equivalent to the predicate devices cleared under the primary predicate device Arthrex Distal Extremity Plate System (K111253) and additional predicate device Arthrex Plates, Screws, and Staples (K150456) in which basic design features, intended use, fundamental scientific technology, plate characteristics, and sterility are identical. <u>Plate Characteristics:</u> • The proposed Arthrex Anatomic Lapidus Plates and I-Beam Lapidus Plates will have a smaller width than the primary predicate device Arthrex Distal Extremity Plate System (K111253). • The proposed Arthrex I-Beam Lapidus Plates will be packaged with additional Class 1 exempt instrumentation; whereas the primary predicate device Arthrex Distal Extremity Plate System (K111253) includes plates that are packaged as standalone. • The proposed Arthrex I-Beam Lapidus Plates have an internal beam that extends below the cortical surface which is different from the primary predicate device Arthrex Distal Extremity Plate System (K111253). <u>Packaging:</u> • The proposed Arthrex Anatomic Lapidus Plates will be packaged in a double poly/Tyvek pouch inside a carton which is equivalent to additional predicate device Arthrex Plates, Screws and Staples (K150456). • The proposed I-Beam Lapidus Plates will be packaged in a double PETG blister tray with Tyvek lidding inside a carton. <u>Sterility:</u>

	• The proposed Arthrex Anatomic Lapidus Plates and I-Beam Lapidus Plates will be offered as sterile which is equivalent to additional predicate device Arthrex Plates, Screws and Staples (K150456). <u>Shelf-Life:</u> • The proposed Arthrex Anatomic Lapidus Plates and I-Beam Lapidus Plates will be offered as sterile (Gamma) which is equivalent to additional predicate device Arthrex Plates, Screws and Staples (K150456). The Arthrex Anatomic Lapidus Plates and I-Beam Lapidus Plates were evaluated for MR Conditional labeling. The predicate devices cleared under the primary predicate device Arthrex Distal Extremity Plate System (K111253) and additional predicate device Arthrex Plates, Screws, and Staples (K150456) were not evaluated for MR Conditional labeling. The Arthrex Anatomic Lapidus Plates and I-Beam Lapidus Plates are substantially equivalent to the predicate devices cleared the primary predicate device Arthrex Distal Extremity Palte System (K111253) and additional predicate device Arthrex Plates, Screws, and Staples (K150456) with minor modifications with no change to the intended use, design, or function. Any differences between the Arthrex Anatomic Lapidus Plates and I-Beam Lapidus Plates and the predicate devices are considered minor and do not raise different questions of safety or effectiveness.
Conclusion	The Arthrex Anatomic Lapidus Plates and I-Beam Lapidus Plates are substantially equivalent to the predicate devices cleared under K111253 and K150456 in which the basic design features and intended use are the same. Based on the 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.