June 25, 2026

Arthrex, Inc.
Konrad Wolfmeyer
Regulatory Affairs Senior Specialist
1370 Creekside Blvd.
Naples, Florida 34108

Re: K260809
Trade/Device Name: Arthrex Sterile VAL and VAL KreuLock™ Compression Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: May 27, 2026
Received: May 27, 2026

Dear Konrad Wolfmeyer:

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,

Tejen D. Soni -S

For
Shumaya Ali, M.P.H.
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.	K260809	?

Please provide the device trade name(s). ?

Arthrex Sterile VAL and VAL KreuLock™ Compression Screw System

Please provide your Indications for Use below. ?

The Arthrex VAL KreuLock Compression Screws (2.7 mm solid) are intended to be used in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, tibia, fibula, femur, pelvis, acetabulum, metacarpals, metatarsals, humerus, radius, ulna, calcaneus, and clavicle. When used with a plate, the screw may be used with the Arthrex Low Profile Plate, Small Fragment Plates, Distal Extremity Plates, Mesh Plates (2.7) and Distal Radius Plates.

The Arthrex VAL KreuLock™ Compression Screws (2.0-3.0 mm solid) are intended to be used in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, tibia, fibula, femur, pelvis, acetabulum, metacarpals, metatarsals, humerus, radius, ulna, calcaneus, clavicle and scapula. When used with a plate, the screw may be used with the Arthrex Low Profile Plate, Small Fragment Plates, Distal Extremity Plates, Mesh Plates (2.7-3.0) and Distal Radius Plates

The Arthrex VAL KreuLock™ Compression Screws (3.5 mm and larger, solid) are intended to be used in a plate screw system for internal bone fixation for bone fractures, fusions, Osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneus, pelvis, acetabulum, metacarpals, metatarsals, femur and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile Plate, Small Fragment Plates, Fracture Plates, Distal Extremity Plates, Distal Radius Plates, Humeral Fracture Plates, Osteotomy Plates, and Ankle Fusion Plates.

The Arthrex Hybrid KreuLock™ Compression Screws (3.5 mm and larger, solid) are intended to be used in a plate-screw system for internal bone fixation for bone fractures, fusions, Osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneus, pelvis, acetabulum, metacarpals, metatarsals, femur and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile Plate, Small Fragment Plates, Fracture Plates, Distal Extremity Plates, Distal Radius Plates, Humeral Fracture Plates, Osteotomy Plates, and Ankle Fusion Plates.

The Arthrex VAL Screws (2.7 mm solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, tibia, fibula, femur, pelvis, acetabulum, metacarpals, metatarsals, humerus, radius, ulna, calcaneus, and clavicle. When used with a plate, the screw may be used with the Arthrex Low Profile Plate, Small Fragment Plates, Distal Extremity Plates, Mesh Plates (2.7-3.0) and Distal Radius Plates.

The Arthrex VAL Screws (3.5 mm and larger, solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneus, pelvis, acetabulum, metacarpals, metatarsals, femur and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile Plate, Small Fragment Plates, Fracture Plates, Distal Extremity Plates, Distal Radius Plates, Humeral Fracture Plates, Osteotomy Plates, and Ankle Fusion Plates.

The Arthrex Hybrid Low Profile VAL Screws (3.5mm and larger, solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneus, pelvis, acetabulum, metacarpals, metatarsals, femur and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile Plate, Small Fragment Plates, Fracture Plates, Distal Extremity Plates, Distal Radius Plates, Humeral Fracture Plates, Osteotomy Plates, and Ankle Fusion Plates.

The Arthrex Low Profile Screws (3.5mm and larger, solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and nonunions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile, Small Fragment Plates, Fracture Plates, Distal Extremity Plates, Humeral Fracture Plates and Osteotomy Plates.

The Arthrex Mini Fragment System is indicated for fracture fixation, reconstruction, replantation, stabilization, reduction, fusions, osteotomies, mal-unions, and non-unions of small bones and small bone fragments including normal and osteopenic bones in adult and adolescent (12-21 years) patients. The system is also indicated for non-load bearing stabilization and reduction of bone fragments in long bones.

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)	?
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)	?

510(k) Summary

Date Prepared	6/23/2026
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Konrad Wolfmeyer Title: Senior Regulatory Affairs Specialist Phone: 1-317-607-4265 Email: Konrad.Wolfmeyer@arthrex.com
Trade Name	Arthrex Sterile VAL and VAL KreuLock™ Compression Screw System
Common Name	Smooth or threaded metallic bone fixation fastener
Product Code	HWC
Regulation Number & Classification Name	21 CFR 888.3040 Screw, Fixation, Bone
Regulatory Class	II
Primary Predicate Device	K243195 Arthrex SS VAL and VAL KreuLock Compression Screw System
Additional Predicate Devices	K241592 Arthrex VAL and VAL KreuLock Compression Screw System K242554 Arthrex VAL and VAL KreuLock Compression Screw System K203294 Arthrex Pilon Fusion System K220937 Arthrex Mini Fragment System
Reference Devices	K201132 Arthrex Compression Screws
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Sterile VAL and VAL KreuLock™ Compression Screw System.
Device Description	The Arthrex VAL KreuLock™ Compression Screws are fracture fixation devices comprised of stainless steel (316L Stainless Steel per ASTM F138) or titanium (Titanium Ti-6AL-4V per ASTM F1472) self-tapping, solid, fully threaded, variable angle locking (VAL) screws that are offered in standard and reinforced configurations. They are offered with a 2.0 mm, 2.7 mm, 3.0 mm or 3.5 mm diameter and range in lengths

from 6 mm to 110 mm. The screws are sold single-use and sterile.

The Arthrex VAL Screws are fracture fixation devices comprised of stainless steel (316L Stainless Steel per ASTM F138) or titanium (Titanium Ti-6AL-4V per ASTM F1472) self-tapping, solid, fully threaded, variable angle locking (VAL) screws that are offered in standard and reinforced configurations. They are offered with a 2.7 mm or 3.5 mm diameter and range in lengths from 8 mm to 110 mm. The screws are sold single-use and sterile.

The Arthrex Hybrid KreuLock™ Compression Screws are fracture fixation devices comprised of titanium (Titanium Ti-6AL-4V per ASTM F1472) self-tapping, solid, fully threaded, variable angle locking (VAL) screws. They consist of existing screws cleared under K201132 and line extension screws with the locking head geometry of the existing 2.7 mm screws and a shaft geometry of the existing 3.5 mm screws. The Arthrex Hybrid KreuLock™ Compression Screws range in length from 12 mm to 80 mm. The screws are sold single-use and sterile.

The Arthrex Hybrid Low Profile VAL Screws are fracture fixation devices comprised of titanium (Titanium Ti-6AL-4V per ASTM F1472) self-tapping, solid, fully threaded, variable angle locking (VAL) screws. They consist of line extension screws with the locking head geometry of the existing 2.7 mm screws and a shaft geometry of the existing 3.5 mm screws. The Arthrex Hybrid Low Profile VAL Screws range in length from 10 mm to 80 mm. The screws are sold single-use and sterile.

The Arthrex Low Profile Screws are fracture fixation devices consisting of fully threaded, solid and non-locking screws. The Arthrex Low Profile Screws are offered with a 3.5 mm diameter and range in lengths

	from 62 mm to 78 mm. The Arthrex Low Profile Screws are a line extension to and fall within the size range of existing screws cleared within K203294. The screws are manufactured from Titanium alloy, Ti-6AL-4V conforming to ASTM F136. The screws are sold single-use and sterile. The Arthrex Cortical Screws are fracture fixation devices consisting of fully threaded, self-tapping screws composed of titanium alloy, Ti-6AL-4V conforming to ASTM F136. The Arthrex Cortical Screws are offered with a 2.7 mm diameter and are 6-80 mm in length. The Arthrex Cortical Screws are sold single-use and sterile.
Indications for Use	The Arthrex VAL KreuLock Compression Screws (2.7 mm solid) are intended to be used in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, tibia, fibula, femur, pelvis, acetabulum, metacarpals, metatarsals, humerus, radius, ulna, calcaneus, and clavicle. When used with a plate, the screw may be used with the Arthrex Low Profile Plate, Small Fragment Plates, Distal Extremity Plates, Mesh Plates (2.7) and Distal Radius Plates. The Arthrex VAL KreuLock™ Compression Screws (2.0-3.0 mm solid) are intended to be used in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, tibia, fibula, femur, pelvis, acetabulum, metacarpals, metatarsals, humerus, radius, ulna, calcaneus, clavicle and scapula. When used with a plate, the screw may be used with the Arthrex Low Profile Plate, Small Fragment Plates, Distal Extremity Plates, Mesh Plates (2.7-3.0) and Distal Radius Plates The Arthrex VAL KreuLock™ Compression Screws (3.5 mm and larger, solid) are intended to be used in a plate screw system for internal bone fixation for bone

	fractures, fusions, Osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneus, pelvis, acetabulum, metacarpals, metatarsals, femur and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile Plate, Small Fragment Plates, Fracture Plates, Distal Extremity Plates, Distal Radius Plates, Humeral Fracture Plates, Osteotomy Plates, and Ankle Fusion Plates. The Arthrex Hybrid KreuLock™ Compression Screws (3.5 mm and larger, solid) are intended to be used in a plate-screw system for internal bone fixation for bone fractures, fusions, Osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneus, pelvis, acetabulum, metacarpals, metatarsals, femur and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile Plate, Small Fragment Plates, Fracture Plates, Distal Extremity Plates, Distal Radius Plates, Humeral Fracture Plates, Osteotomy Plates, and Ankle Fusion Plates. The Arthrex VAL Screws (2.7 mm solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, tibia, fibula, femur, pelvis, acetabulum, metacarpals, metatarsals, humerus, radius, ulna, calcaneus, and clavicle. When used with a plate, the screw may be used with the Arthrex Low Profile Plate, Small Fragment Plates, Distal Extremity Plates, Mesh Plates (2.7-3.0) and Distal Radius Plates. The Arthrex VAL Screws (3.5 mm and larger, solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon,

	humerus, radius, ulna, tibia, calcaneus, pelvis, acetabulum, metacarpals, metatarsals, femur and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile Plate, Small Fragment Plates, Fracture Plates, Distal Extremity Plates, Distal Radius Plates, Humeral Fracture Plates, Osteotomy Plates, and Ankle Fusion Plates. The Arthrex Hybrid Low Profile VAL Screws (3.5mm and larger, solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneus, pelvis, acetabulum, metacarpals, metatarsals, femur and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile Plate, Small Fragment Plates, Fracture Plates, Distal Extremity Plates, Distal Radius Plates, Humeral Fracture Plates, Osteotomy Plates, and Ankle Fusion Plates. The Arthrex Low Profile Screws (3.5mm and larger, solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and nonunions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile, Small Fragment Plates, Fracture Plates, Distal Extremity Plates, Humeral Fracture Plates and Osteotomy Plates. The Arthrex Mini Fragment System is indicated for fracture fixation, reconstruction, replantation, stabilization, reduction, fusions, osteotomies, mal-unions, and non-unions of small bones and small bone fragments including normal and osteopenic bones in adult and adolescent (12-21 years) patients. The system

	is also indicated for non-load bearing stabilization and reduction of bone fragments in long bones.
Performance Data	The proposed Arthrex Sterile VAL and VAL KreuLock™ Compression Screw System consists of sterile versions of screws that have already been cleared by the FDA under primary and additional predicate devices K241592, K242554, K243195 and K220937. Since the sterile and non-sterile versions share identical fit, form, and function, and sterilization does not affect the strength of the devices, the testing performed in the previously cleared 510(k)s are also applicable to the subject devices.
Technological Comparison	The Arthrex Sterile VAL and VAL KreuLock™ Compression Screw System is substantially equivalent to the primary predicate device primary predicate device (K243195) and additional predicate devices (K241592, K242554, K203294 and K220937) in which the basic design features and fundamental scientific technology are equivalent. The Arthrex Sterile VAL and VAL KreuLock™ Compression Screw System is manufactured from stainless steel and titanium, which is the same materials as the primary predicate device (K243195) and additional predicate devices (K241592, K242554, K203294 and K220937). The Arthrex Sterile VAL and VAL KreuLock™ Compression Screw System consist of sterile versions of the non-sterile screws cleared within primary predicate device (K243195) and additional predicate devices (K241592, K242554, K203294 and K220937). The Arthrex Sterile VAL and VAL KreuLock™ Compression Screw System is packaged in a different packaging configuration than the non-sterile screws cleared within the primary predicate device (K243195) and additional predicate devices (K241592, K242554, K203294 and K220937).

	The Arthrex Sterile VAL and VAL KreuLock™ Compression Screw System is offered with a different shelf life than the shelf life of the non-sterile screws cleared within the primary predicate device (K243195) and additional predicate devices (K241592, K242554, K203294 and K220937). The Arthrex Sterile VAL and VAL KreuLock™ Compression Screw System was evaluated for MR Conditional safety. The primary predicate device (K243195) and additional predicate devices (K241592, K242554, K203294 and K220937) were also evaluated for MR Conditional safety.
Conclusion	Based on the intended use, fundamental scientific technology, and the data provided in this Traditional 510(k), Arthrex has determined that the proposed Arthrex Sterile VAL and VAL KreuLock™ Compression Screw System is substantially equivalent to the primary predicate device Arthrex SS VAL and VAL KreuLock Compression Screw System (K243195) and additional predicate devices Arthrex VAL and VAL KreuLock Compression Screw System (K241592), Arthrex VAL and VAL KreuLock Compression Screw System (K242554), Arthrex Pilon Fusion System (K203294) and Arthrex Mini Fragment System (K220937). Any differences between the proposed and predicate devices are considered minor and do not raise different questions concerning safety and effectiveness.