



August 31, 2024

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

Re: K241592

Trade/Device Name: Arthrex 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, HRS
Dated: May 31, 2024
Received: June 3, 2024

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 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 Ferreria, 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

Submission Number (if known)

K241592

Device Name

Arthrex VAL and VAL KreuLock™ Compression Screw System

Indications for Use (Describe)

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 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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K241592 510(k) Summary

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| <i>Date Prepared</i> | August 29, 2024 |
| <i>Submitter</i> | Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 |
| <i>Contact Person</i> | Name: Konrad Wolfmeyer Title: Senior Regulatory Affairs Specialist Phone: 1-317-607-4265 Email: Konrad.Wolfmeyer@arthrex.com |
| <i>Trade Name</i> | Arthrex VAL and VAL KreuLock™ Compression Screw System |
| <i>Common Name</i> | Arthrex VAL and VAL KreuLock™ Compression Screw System |
| <i>Product Code</i> | HWC |
| <i>Classification Name</i> | 21 CFR 888.3040 Screw, Fixation, Bone |
| <i>Regulatory Class</i> | II |
| <i>Primary Predicate Device</i> | K201132 Arthrex Compression Screws |
| <i>Additional Predicate Device(s)</i> | K103705 Arthrex Low Profile Screws K143614 Arthrex Low Profile VAL Screw |
| <i>Reference Device</i> | K082516 Smith & Nephew PERI-LOC Hexalobular Bone Screws |
| <i>Purpose of Submission</i> | This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex VAL and VAL KreuLock™ Compression Screw System |
| <i>Device Description</i> | <p>The Arthrex VAL 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 screws that are offered in standard and reinforced configurations. They are offered with a 3.5 mm diameter and the standard versions range in lengths from 10 mm to 90 mm while the reinforced versions range in lengths from 10 mm to 110 mm. The reinforced configurations have a larger minor diameter with the same major diameter as the standard configurations.</p> <p>The Arthrex VAL Screws are fracture fixation devices comprised of titanium (Titanium Ti-6AL-4V per ASTM F1472) self-tapping, solid, fully threaded, variable angle locking screws that are offered in standard and reinforced configurations. They are offered with a 3.5 mm diameter and range in lengths from 10 mm to 110 mm. The reinforced configurations have a larger minor</p> |

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| | <p>diameter with the same major diameter as the standard configurations.</p> |
| <p>Indications for Use</p> | <p>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.</p> <p>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, calcaneous, 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.</p> |
| <p>Performance Data</p> | <p>Arthrex conducted pullout testing, cantilever testing, pushout testing, head locking testing, compression testing, torque testing, axial pullout analysis, torsional strength testing, and driving torque testing was conducted in accordance with ASTM F543 Standard Specification and Test Methods for Metallic Medical Bone Screws on the proposed Arthrex VAL and VAL KreuLock™ Compression Screw Systems to demonstrate that the change do not affect performance and the proposed devices are substantially equivalent to the primary predicate device.</p> <p>MRI force, torque, and image artifact testing were conducted in accordance with FDA guidance <i>Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment</i>, ASTM F2052 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic</p> |

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.

Technological Comparison

The Arthrex VAL and VAL KreuLock™ Compression Screw System is substantially equivalent to the predicate devices cleared under K201132 in which the basic design features, fundamental scientific technology, materials, shelf-life (non-sterile only), and sterility (non-sterile only) are identical.

The Arthrex VAL and VAL KreuLock™ Compression Screw System is manufactured from titanium, which is the same material as the primary predicate device cleared under K201132.

The Arthrex VAL and VAL KreuLock™ Compression Screw System devices have the same sterility, non-sterile, as the primary predicate cleared under K201132.

The Arthrex VAL and VAL KreuLock™ Compression Screw System devices have the same packaging as the primary predicate cleared under K201132.

The Arthrex VAL and VAL KreuLock™ Compression Screw System devices have the same shelf-life, unlimited, as the primary predicate cleared under K201132.

The Arthrex VAL and VAL KreuLock™ Compression Screw System devices have the same fundamental scientific technology as the primary predicate cleared under K201132.

The Arthrex VAL and VAL KreuLock™ Compression Screw System devices were evaluated for MRI Conditional labeling, which is the same as the primary predicate cleared under K201132.

The Arthrex VAL and VAL KreuLock™ Compression Screw System devices have an indications for use that differs from the primary predicate cleared under K201132.

The Arthrex VAL and VAL KreuLock™ Compression Screw System devices are offered in longer lengths than the primary predicate cleared under K201132.

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| | <p>The Arthrex VAL and VAL KreuLock™ Compression Screw System is substantially equivalent to the predicate devices cleared under K201132. Any differences between the Arthrex VAL and VAL KreuLock™ Compression Screw System and the predicate device cleared under K201132 are considered minor and do not raise different questions of safety or effectiveness.</p> |
| Conclusion | <p>Based on the intended use, fundamental scientific technology, and the data provided in this this Traditional 510(k), Arthrex has determined that the Arthrex VAL and VAL KreuLock™ Compression Screw System is substantially equivalent to the predicate devices. Any differences between the proposed and predicate devices are considered minor and do not raise different questions concerning safety and effectiveness.</p> |