May 22, 2025

Arthrex, Inc.
Kristi Frisch
Principal, Regulatory Affairs Specialist
1370 Creekside Blvd.
Naples, Florida 34108

Re: K250920
Trade/Device Name: Arthrex Spine Compression FT Screw
Regulatory Class: Unclassified
Product Code: MRW, HWC
Dated: March 26, 2025
Received: March 27, 2025

Dear Kristi Frisch:

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,

Colin O'neill -S

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250920

Device Name
Arthrex Spine Compression FT Screw

Indications for Use *(Describe)*
The Arthrex Spine Compression FT Screws are intended to stabilize the spine as an aid to fusion through immobilization of the facet joints, either through bilateral transfacet fixation, or unilateral transfacet fixation when used contralateral to pedicle screw fixation. The Arthrex Spine Compression FT Screws are intended to be used with or without bone graft, at a single or multiple levels, from C2 to S1, for treatment of any or all of the following: pseudoarthrosis and failed previous fusions which are symptomatic or which may cause secondary instability or deformity; spondylolisthesis; spondylolysis; degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies; degeneration of the facets with instability and trauma including spinal fractures and/or dislocations.
The Arthrex Spine Compression FT Screw is also indicated for fracture fixation of small bones and bone fragments including pars interarticularis and odontoid. The fracture fixation of pars interarticularis is indicated for the adult and adolescent population (12 to 21 years of age).

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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510(k) Summary

Date Prepared	May 20, 2025
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Kristi Frisch Title: Principal, Regulatory Affairs Specialist, Spine/Vet Phone: 1-239-598-4302 x73849 Email: Kristi.Frisch@Arthrex.com
Trade Name	Arthrex Spine Compression FT Screw
Common Name	Facet Screw
Product Codes	MRW, HWC
Classifications	- Unclassified (Product Code: MRW) - 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener, Class II (Product Code: HWC) - Panel Code 87
Predicate Devices	CORRIDOR Fixation System, Globus Medical Inc.(K192744) (Primary Predicate) Arthrex Compression FT Screw (K201132) (Additional Predicate)
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Spine Compression FT Screws for spine indications.
Device Description	The Arthrex Spine Compression FT Screws are headless, threaded, cannulated titanium implants that are available in a variety of sizes. The screws have a fully threaded screw shaft with a tapering head and a variable-stepped thread pitch that allows the screw the ability to provide compression and stability between bony fragments or joints.
Indications for Use	The Arthrex Spine Compression FT Screws are intended to stabilize the spine as an aid to fusion through immobilization of the facet joints, either through bilateral transfacet fixation, or unilateral transfacet fixation when used contralateral to pedicle screw fixation. The Arthrex Spine Compression FT Screws are intended to be used with or without bone graft, at a single or multiple levels, from C2 to S1, for treatment of any or all of the following: pseudoarthrosis and failed previous fusions which are symptomatic or which may cause secondary instability or deformity; spondylolisthesis; spondylolysis; degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies; degeneration of the facets with instability and trauma including spinal fractures and/or dislocations. The Arthrex Spine Compression FT Screw is also indicated for fracture fixation of small bones and bone fragments including pars interarticularis and odontoid. The fracture fixation of

	pars interarticularis is indicated for the adult and adolescent population (12 to 21 years of age).
Performance Data	Arthrex conducted axial push-out and static cantilever bending in accordance with in conformance with the FDA currently recognized version of ASTM F2193 Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System-Annex 4: Test Method for Measuring the static and fatigue bending strength of metallic spinal screws on the subject Arthrex Spine Compression FT Screws to demonstrate performance is substantially equivalent to the predicate devices. Arthrex has conducted the recommended non-clinical testing per the FDA Guidance, "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment", which includes magnetically induced displacement force, magnetically induced torque, heating by RF fields, and image artifact (set up and parameters may not be the same). In addition, Arthrex has performed in vivo electromagnetic simulation to further establish the safety and compatibility of the system in MR environment. The maximum mass of the Arthrex Spine Compression FT Screw is less than that of the worst-case construct previously tested of the Arthrex Compression FT Screw family. Therefore, the system does not represent a new worst-case in terms of MR compatibility compared to the modeled implants for force, torque, and image artifact testing. Radio frequency induced heating was evaluated using ASTM F2182-19 Test Method for Measurement of Radio Frequency Induced Heating near Passive Implants during Magnetic Resonance Imaging and Guidance for FDA, Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices. Image artifact was evaluated using ASTM F2119-13, Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants. A clinical literature summary was provided to support the expansion of indications. The subject Arthrex Spine Compression FT Screw device testing performance characteristics, fall within the scope of FDA's Facet Screw Systems – Performance Criteria for Safety and Performance Based Pathway Guidance for Industry and Food and Drug Administration Staff Document issued on April 13, 2022.
Technological Comparison	The Arthrex Spine Compression FT Screw System has the same intended use/indications, fundamental scientific technology, materials, sterility, and packaging method as the predicates

	Corridor Fixation System (K192744) and Arthrex Compression FT Screw (K201132, K182361, K170382, K150456, K132217) devices.
Conclusion	Based on the intended use, fundamental scientific technology, and the data provided in this Traditional 510(k), Arthrex has determined that the Arthrex Spine Compression FT Screws are substantially equivalent to the predicate device. Any differences between the proposed and predicate device are considered minor and do not raise different questions concerning safety and effectiveness.