



September 24, 2026

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

Re: K262618
Trade/Device Name: Arthrex Spine Compression FT Screw
Regulatory Class: Unclassified
Product Code: MRW, HWC
Dated: July 28, 2026
Received: July 28, 2026

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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,

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

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.

K262618

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Please provide the device trade name(s).

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Arthrex Spine Compression FT Screw

Please provide your Indications for Use below.

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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).

Please select the types of uses.

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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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)

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510(k) Summary

<i>Date Prepared</i>	July 27, 2026
<i>Submitter</i>	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
<i>Contact Person</i>	Name: Kristi Frisch Title: Principal, Regulatory Affairs Specialist, Spine/Vet Phone: 1-239-598-4302 x73849 Email: Kristi.Frisch@Arthrex.com
<i>Trade Name</i>	Arthrex Spine Compression FT Screw
<i>Common Name</i>	Facet Screw
<i>Product Code</i>	MRW, HWC
<i>Classification Name</i>	- Unclassified (Product Code: MRW) - 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener, Class II (Product Code: HWC) - Panel Code 87
<i>Regulatory Class</i>	Class II
<i>Primary Predicate Device</i>	Arthrex Spine Compression FT Screw K250920 (S.E. May 22, 2025)
<i>Reference Devices</i>	Arthrex Univers Revers Monoblock Stem K230366 (S.E. April 10, 2023)
<i>Purpose of Submission</i>	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Spine Compression FT Screws with hydroxyapatite (HA) coating.
<i>Device Description</i>	The subject device Arthrex Spine Compression FT Screws are nearly identical to the cleared Arthrex predicate Spine Compression FT Screws. (K250920, S.E. 05/22/2025). The only modification is the addition of hydroxyapatite (HA) coating material to the threaded surface of the predicate screws. 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.

<i>Indications for Use</i>	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).
<i>Performance Data</i>	The subject HA-coated Arthrex Spine Compression FT Screws underwent new testing (axial pushout, static bending, and insertion torque) in conformance with the FDA currently recognized version of ASTM F2193. Testing was performed on final, finished devices. The testing demonstrates the addition of the Hydroxyapatite coating (HA) to the Arthrex Spine Compression FT Screw device (K250920) did not substantially impact the mechanical performance. Tensile testing was performed to test the adhesion strength of the HA coating. Test results met prespecified acceptance criteria.

<i>Technological Comparison</i>	The subject HA-coated Arthrex Spine Compression FT Screws have the same intended use/indications, fundamental scientific technology, materials, and sterility as the primary predicate. The only modification is the addition of hydroxyapatite (HA) coating material to the threaded surface.
<i>Conclusion</i>	Based on the intended use, fundamental scientific technology, and the data provided in this Traditional 510(k), Arthrex has determined that the HA coated 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.