



September 25, 2026

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

Re: K262975

Trade/Device Name: Arthrex Beaming System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: August 26, 2026
Received: August 26, 2026

Dear Mr. 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.

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,

 Shumaya Ali -S

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.

K262975

?

Please provide the device trade name(s).

?

Arthrex Beaming System

Please provide your Indications for Use below.

?

The Arthrex Beaming System is intended to be used in the stabilization, reconstruction, and fixation of bone fractures, fusions, osteotomies, and non-unions in the foot and ankle.

Please select the types of uses.

☒ 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	9/17/2026
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 Beaming System
Common Name	Screw, Fixation, Bone
Product Code	HWC
Regulation Number & Classification Name	21 CFR 888.3040 Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class	II
Predicate Device	K254215 Arthrex Beaming System
Device Description	The Arthrex Beaming System is a fixation device system comprised of stainless steel (316L Stainless Steel per ASTM F138), available in both a cannulated and solid option. The Beams range from 5 mm to 8 mm in diameter and from 50 mm to 170 mm in length. The Arthrex Beaming System consist of single-use, Gamma sterilized devices packaged in a double PETG blister tray with Tyvek lidding and non-sterile devices intended for end-user sterilization packaged in a polyethylene bag.
Indications for Use	The Arthrex Beaming System is intended to be used in the stabilization, reconstruction, and fixation of bone fractures, fusions, osteotomies, and non-unions in the foot and ankle.
Technological Comparison	<u>Intended Use Comparison Section:</u> Compared to the predicate device, the proposed Arthrex Beaming System remains unchanged with respect to its intended use/indications for use. <u>Technological Comparison Section:</u> Compared to the predicate device, the proposed Arthrex Beaming System remains unchanged with respect to its

	basic design features (except for the solid tip design), sizes, fundamental scientific technology, packaging configuration, sterility, shelf life, and MRI compatibility. The differences between the predicate device, Arthrex Beaming System, K254215, and the proposed Arthrex Beaming System are as follows: Since the K254215 clearance, a design change to the tip of the solid Arthrex Beams was implemented. There was no change in labeling, sterilization, packaging, material or performance. The original testing reviewed and cleared by the FDA in predicate device K254215 used a 30 pcf polyurethane foam substrate. The subject 510(k) testing uses sequential 15 and 20 pcf foam blocks to represent the metatarsal/cuneiform and navicular/talus regions, respectively. This change provides a more anatomically representative test configuration while testing the same device sizes, ASTM F543 test methods, sample sizes, failure torque testing, and failure torque to insertion torque ratio and failure torque to removal torque ratio acceptance criteria.
<i>Performance Data</i>	Arthrex conducted failure torque testing with a more clinically relevant test setup and the results demonstrated that the performance of the proposed devices are substantially equivalent to the predicate devices in a more clinically relevant situation. Additionally, based on an engineering assessment, the tip design modification was determined not to adversely affect the mechanical performance of the proposed devices compared to the predicate devices. Therefore, no additional performance testing specific to the tip design change was conducted as part of this submission. No MRI testing was performed for this submission. The modifications included in this submission do not affect the previously established MRI safety profile of the devices.

	The existing MRI parameters and labeling previously cleared under the predicate device, Arthrex Beaming System (K254215), remain applicable and are supported by the previously completed MRI evaluations.
<i>Conclusion</i>	Based on the intended use, fundamental scientific technology, and the data provided in this Special 510(k), Arthrex has determined that the proposed Arthrex Beaming System is substantially equivalent to the predicate device Arthrex Beaming System (K254215). Any differences between the proposed and predicate devices are considered minor and do not raise different questions concerning safety and effectiveness.