May 8, 2026

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

Re: K254215
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: April 10, 2026
Received: April 10, 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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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.	K254215

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 (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Date Prepared	May 1, 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
Classification Name	21 CFR 888.3040 Screw, Fixation, Bone
Regulatory Class	II
Primary Predicate Device	K201132 Arthrex Compression Screws
Reference Devices	K140741 Wright Medical Technology, Inc. SALVATION Beams and Bolts K082516 DePuy Synthes 6.5mm Midfoot Fusion Bolt
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Beaming System
Device Description	The Arthrex Beaming System is a stabilization, reconstruction, and fixation device system comprised of stainless steel (316L Stainless Steel per ASTM F138), available in both a cannulated and solid option. They are fully-threaded and headless with variable pitch. The Arthrex Beaming System devices range from 5 mm to 8 mm in diameter and from 50 mm to 170 mm in length
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.
Performance Data	Arthrex conducted Axial Pull-Out, Static 4-Point Bending, Fatigue 4-Point Bending, Torque, and Double Shear testing conducted in accordance with ASTM F543-23, *Standard Specification and Test Methods for*

	Metallic Medical Bone Screws, and ASTM F1264-24, *Standard Specification and Test Methods for Intramedullary Fixation Devices* on the proposed Arthrex Beaming System to demonstrate that the change do not affect performance and the proposed devices are substantially equivalent to the primary predicate devices. MRI force, torque, and image artifact testing were conducted in accordance with FDA guidance *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*, ASTM F2052 *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic 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*. A manufacturing justification was leveraged to support biocompatibility of the proposed Arthrex Beaming System. Evaluation of the sterility, shelf-life, and packaging of the Arthrex Beaming System leveraged identical cleaning, sterilization, and packaging from the primary predicate device, Arthrex Compression Screws (K201132).
Technological Comparison	The Arthrex Beaming Systems is substantially equivalent to the primary predicate device Arthrex Compression Screws (K201132) in which the basic design features and fundamental scientific technology are equivalent. The Arthrex Beaming System is manufactured from stainless steel, which is the same material as the primary predicate device Arthrex Compression Screws

	(K201132) and reference devices DePuy Synthes 6.5mm Midfoot Fusion Bolt (K081071). The Arthrex Beaming System will be offered in additional diameters outside of the diameters offered for the primary predicate device Arthrex Compression Screws (K201132). The Arthrex Beaming System will be offered in longer lengths than the lengths offered for the primary predicate device Arthrex Compression Screws (K201132). The non-sterile and sterile Arthrex Beaming System device packaging is equivalent to the non-sterile and sterile packaging offered for primary predicate device Arthrex Compression Screws (K201132). The Arthrex Beaming System will be offered as non-sterile and sterile which is equivalent to the primary predicate device Arthrex Compression Screws (K201132). The non-sterile Arthrex Beaming System is offered with a shelf-life which is equivalent to primary predicate device Arthrex Compression Screws (K201132), and the sterile Arthrex Beaming System is offered with a shelf-life which is equivalent to the primary predicate device Arthrex Compression Screws (K201132). The Arthrex Beaming System was evaluated for MR Conditional safety. The primary predicate device Arthrex Compression Screws (K201132) was also evaluated for MR Conditional safety. The Arthrex Beaming System is substantially equivalent to the predicate devices cleared under K201132. Any differences between the Arthrex Beaming System and the predicate device cleared under K201132 are

	considered minor and do not raise different questions of safety or effectiveness.
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 Beaming System is substantially equivalent to the primary predicate devices. Any differences between the proposed and predicate devices are considered minor and do not raise different questions concerning safety and effectiveness.