

September 1, 2026

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

Re: K262451
Trade/Device Name: Arthrex DynaNite Staples
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: JDR
Dated: July 16, 2026
Received: July 17, 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 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,

RYAN TROMBETTA -S

For: Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint Arthroplasty 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.	K262451

Please provide the device trade name(s).

Arthrex DynaNite Staples

Please provide your Indications for Use below.

The DynaNite nitinol staple, DynaNite SuperMX staple, DynaNite® WideLeg Staples, DynaNite® MX4™ Staples and DynaNite® Reduction Staples are intended to be used for fixation such as: Lisfranc arthrodesis, mono or bi-cortical osteotomies in the forefoot, first metatarsophalangeal arthrodesis, Akin osteotomy, midfoot and hindfoot arthrodeses or osteotomies, fixation of osteotomies for hallux valgus treatment (Scarf and Chevron), and arthrodesis of the metatarsocuneiform joint to reposition and stabilize metatarsus primus varus.

The DynaNite nitinol staple, DynaNite SuperMX staple, DynaNite® WideLeg Staples, DynaNite® MX4™ Staples and DynaNite® Reduction Staples are indicated for:
• Fracture and osteotomy fixation and joint arthrodesis of the hand and foot.
• Fixation of proximal tibial metaphysis osteotomy.
• Hand and foot bone fragment and osteotomy fixation and joint arthrodesis.
• Fixation of small bone fragments (i.e. small fragments of bone which are not comminuted to the extent to preclude staple placement). These fragments may be located in long bones such as femur, fibula and tibia in the lower extremities; the humerus, ulna or radius in the upper extremities; the clavicle and ribs; and in flat bone such as the pelvis, scapula and sternum.
• When used with Arthrex FiberTape Cerclage System, the Arthrex DynaNite nitinol staple (sizes 13x10 and 15x12 only) is intended for sternotomy indications including the "rewiring" of osteotomized sternums.

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	8/28/2026
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 DynaNite Staples
Common Name	Staple, Fixation, Bone
Product Code	JDR
Regulation Number & Classification Name	21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class	II
Primary Predicate Device	K203180 Arthrex DynaNite Nitinol Staples
Additional Predicate Device	K172052 Arthrex DynaNite Nitinol Staple
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex DynaNite Staples.
Device Description	The Arthrex DynaNite Staples are bone fixation devices manufactured from Nickel Titanium (Nitinol) conforming to ASTM F2063 intended to be permanently implanted. The implant is formed with two or four legs connected by a bridge and is offered in multiple combinations of bridge widths, leg lengths, and cross sections to accommodate various anatomies. The Arthrex DynaNite Staples are sold sterile and are single-use.
Indications for Use	The DynaNite nitinol staple, DynaNite SuperMX staple, DynaNite® WideLeg Staples, DynaNite® MX4™ Staples and DynaNite® Reduction Staples are intended to be used for fixation such as: Lisfranc arthrodesis, mono or bi-cortical osteotomies in the forefoot, first metatarsophalangeal arthrodesis, Akin osteotomy, midfoot and hindfoot arthrodeses or osteotomies, fixation of osteotomies for hallux valgus treatment (Scarf and Chevron), and

	arthrodesis of the metatarsocuneiform joint to reposition and stabilize metatarsus primus varus. The DynaNite nitinol staple, DynaNite SuperMX staple, DynaNite® WideLeg Staples, DynaNite® MX4™ Staples and DynaNite® Reduction Staples are indicated for: • Fracture and osteotomy fixation and joint arthrodesis of the hand and foot. • Fixation of proximal tibial metaphysis osteotomy. • Hand and foot bone fragment and osteotomy fixation and joint arthrodesis. • Fixation of small bone fragments (i.e. small fragments of bone which are not comminuted to the extent to preclude staple placement). These fragments may be located in long bones such as femur, fibula and tibia in the lower extremities; the humerus, ulna or radius in the upper extremities; the clavicle and ribs; and in flat bone such as the pelvis, scapula and sternum. • When used with Arthrex FiberTape Cerclage System, the Arthrex DynaNite nitinol staple (sizes 13x10 and 15x12 only) is intended for sternotomy indications including the “rewiring“ of osteotomized sternums.
Performance Data	Arthrex conducted Axial Pull-Out, Static 4-Point Bend, and Fatigue 4-Point Bend testing in accordance with ASTM F564-24, Standard Specification and Test Methods for Metallic Bone Staples, and conducted Corrosion Testing and Transformation Temperature Testing in accordance with ASTM F2129-25, Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices, and ASTM F2082/F2082M-23, Standard Test Method for Determination of Transformation Temperature of Nickel-Titanium Shape Memory Alloys by Bend and Free Recovery, on the proposed Arthrex DynaNite Staples to demonstrate that

	the changes do not affect performance and the proposed devices are substantially equivalent to the 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.
Technological Comparison	Intended Use Comparison Section: The intended use and indications for use of the proposed Arthrex DynaNite Staples is equivalent to the primary predicate device, Arthrex DynaNite Nitinol Staples (K203180) and additional predicate device, Arthrex DynaNite Nitinol Staple (K172052). Technological Comparison Section: The proposed Arthrex DynaNite Staples are substantially equivalent to the primary predicate device, Arthrex DynaNite Nitinol Staples (K203180) and additional predicate device, Arthrex DynaNite Nitinol Staple (K172052) in which the basic design features and fundamental scientific technology are equivalent. The proposed Arthrex DynaNite Staples are manufactured from ASTM F2063 Superelastic Nitinol, which is identical to the material of the primary predicate device, Arthrex DynaNite Nitinol Staples (K203180) and additional

	predicate device, Arthrex DynaNite Nitinol Staple (K172052). The proposed Arthrex DynaNite Staples will be offered with four leg staple options while the primary predicate device, Arthrex DynaNite Nitinol Staples (K203180) and additional predicate device, Arthrex DynaNite Nitinol Staple (K172052) only have two leg staple options. The proposed Arthrex DynaNite Staples have legs that are fully transformed at room temperature which is identical to primary predicate device, Arthrex DynaNite Nitinol Staples (K203180) and additional predicate device, Arthrex DynaNite Nitinol Staple (K172052). The proposed Arthrex DynaNite WideLeg and Reduction Staples include bridge length sizes are identical to and within the size range cleared under primary predicate device, Arthrex DynaNite Nitinol Staples (K203180) and additional predicate device, Arthrex DynaNite Nitinol Staple (K172052). The proposed Arthrex DynaNite MX4 Staples include bridge length sizes outside of the size range cleared under primary predicate device, Arthrex DynaNite Nitinol Staples (K203180) and additional predicate device, Arthrex DynaNite Nitinol Staple (K172052). The proposed Arthrex DynaNite WideLeg and Reduction Staples include a bridge height within the range of the bridge heights cleared under primary predicate device, Arthrex DynaNite Nitinol Staples (K203180). The proposed Arthrex DynaNite MX4 Staples have a bridge height outside of the bridge heights cleared under primary predicate device, Arthrex DynaNite Nitinol Staples (K203180) and additional predicate device, Arthrex DynaNite Nitinol Staple (K172052). The proposed Arthrex DynaNite Reduction Staples include a bridge width equivalent to the bridge width cleared

	under primary predicate device, Arthrex DynaNite Nitinol Staples (K203180) and additional predicate device, Arthrex DynaNite Nitinol Staple (K172052). The proposed Arthrex DynaNite WideLeg and MX4 Staples include bridge widths outside of the bridge width cleared under primary predicate device, Arthrex DynaNite Nitinol Staples (K203180) and additional predicate device, Arthrex DynaNite Nitinol Staple (K172052). The proposed Arthrex DynaNite Staples (all families) include leg length size range that is within the range of the leg length sizes cleared under primary predicate device, Arthrex DynaNite Nitinol Staples (K203180) and additional predicate device, Arthrex DynaNite Nitinol Staple (K172052). The proposed Arthrex DynaNite WideLeg and MX4 Staples have leg angles within the range of leg angles cleared under primary predicate device, Arthrex DynaNite Nitinol Staples (K203180) and additional predicate device, Arthrex DynaNite Nitinol Staple (K172052). The proposed Arthrex DynaNite Reduction Staples have a leg angle outside of the leg angles cleared under primary predicate device, Arthrex DynaNite Nitinol Staples (K203180) and additional predicate device, Arthrex DynaNite Nitinol Staple (K172052). The proposed Arthrex DynaNite Staples packaged individually will consist of a PU pouch inserted into a double Nylon pouch. This is different from primary predicate device, Arthrex DynaNite Nitinol Staples (K203180) and additional predicate device, Arthrex DynaNite Nitinol Staple (K172052). The proposed Arthrex DynaNite Staples packaged with instrumentation consist of a double PETG blister tray with Tyvek lidding. This is identical to the packaging configurations cleared under primary predicate device, Arthrex DynaNite Nitinol Staples (K203180) and additional predicate device, Arthrex DynaNite Nitinol Staple (K172052).

	The proposed Arthrex DynaNite Staples will be offered as sterile which is identical to the primary predicate device, Arthrex DynaNite Nitinol Staples (K203180) and additional predicate device, Arthrex DynaNite Nitinol Staple (K172052). The proposed Arthrex DynaNite Staples are offered with a shelf-life of 5 years which is identical to the primary predicate device, Arthrex DynaNite Nitinol Staples (K203180).
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 DynaNite Staples are substantially equivalent to the predicate devices cleared under K172052 and K203180. Any differences between the proposed and predicate devices are considered minor and do not raise different questions concerning safety and effectiveness.