



January 31, 2025

Arthrex Inc.
Rebecca R. Homan
Manager, Regulatory Affairs - Product Development
1370 Creekside Blvd.
Naples, Florida 34108

Re: K243742

Trade/Device Name: Arthrex DynaNite Nitinol 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, JDQ
Dated: December 3, 2024
Received: December 4, 2024

Dear Rebecca R. Homan:

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,

Limin Sun -S

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

Submission Number (if known)

K243742

Device Name

Arthrex DynaNite Nitinol Staples

Indications for Use (Describe)

The Arthrex DynaNite Nitinol Staple is 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 Arthrex DynaNite Nitinol 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.

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	January 31, 2025
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Rebecca R. Homan Manager, Regulatory Affairs 239-598-4302 ex. 73429 Rebecca.Homan@Arthrex.com
Trade Name	Arthrex DynaNite Nitinol Staples
Common Name	Staple, Fixation, Bone
Product Code	JDR, JDQ
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 Staple
Additional Predicate Devices	K172052 – Arthrex DynaNite Nitinol Staple K232755 – Arthrex FiberTape and TigerTape Cerclage Sutures K230976 – Arthrex Radiopaque FiberTape Cerclage Sutures
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to expand the indications for use for the Arthrex DynaNite Nitinol Staples.
Device Description	The Arthrex DynaNite Nitinol Staples are Nickel Titanium (Nitinol) bone fixation devices intended to be permanently implanted. The implant is formed with two legs connected by a bridge and is offered in multiple combinations of bridge widths, leg lengths, and cross sections to accommodate various anatomy.
Indications for Use	The Arthrex DynaNite Nitinol Staple is 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 Arthrex DynaNite Nitinol 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	Cyclic/Fatigue construct testing was conducted to demonstrate that when used with the Arthrex Cerclage Sutures, the Arthrex DynaNite Nitinol Staples perform substantially equivalent to the Arthrex Cerclage Suture construct for sternal closure. MRI force, torque, and image artifact testing were conducted in accordance with FDA guidance <i>Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment</i>, ASTM F2052 <i>Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment</i>, ASTM F2119 <i>Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants</i>, ASTM F2182 <i>Standard Test Method for Measurement of Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging</i> and ASTM F2213 <i>Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment</i>.

	Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications.
<i>Technological Comparison</i>	The proposed devices are identical in technological characteristics (device design, sterilization, packaging, and biocompatibility). The proposed modification consists of the additional indication of sternotomy indications.
<i>Conclusion</i>	The Arthrex DynaNite Nitinol Staples are substantially equivalent to the predicate device in which the basic design features and intended use are the same. Any differences between the proposed device and the predicate are considered minor and do not raise any new or different questions concerning safety and effectiveness. Based on the indications for use, technological characteristics, and the data submitted, Arthrex Inc. has determined that the proposed device is substantially equivalent to the currently marketed predicate device.