Arthrex Inc.
Rebecca Homan
Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, Florida 34108-1945

December 16, 2020

Re: K203180
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
Dated: October 26, 2020
Received: October 27, 2020

Dear Rebecca 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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Vesa Vuniqi
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K203180

Device Name
Arthrex DynaNite Nitinol Staples

Indications for Use *(Describe)*
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 extend to preclude staple placement). These fragments may be located in long bones such as the 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.

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	October 20, 2020
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Rebecca R. Homan Regulatory Affairs Specialist 1-239-643-5553, ext. 73429 rebecca.homan@arthrex.com
Name of Device	Arthrex DynaNite Nitinol Staples
Common Name	Staple, Fixation, Bone
Product Code	JDR
Classification Name	21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class	II
Predicate Device	K142292: BME, Inc. Speed, Speed Shift, Speed Titan, Speed Arc
Reference Device	K172052: Arthrex DynaNite Nitinol Staple K993714: BME, Inc. Memograph Staple System (OSStaple)
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain expanded 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 anatomies.
Indications for Use	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 extend to preclude staple placement). These fragments may be located in long bones such as the 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.
Performance Data	Pull-out (ASTM F564), Static Four-Point Bend (ASTM F564), Four-Point Bend Fatigue (ASTM F564), Cyclic Potentiodynamic Polarization Corrosion (ASTM F2129) and Transformation Temperature (ASTM F2082/F2082M) testing was conducted to demonstrate that the Arthrex DynaNite Nitinol Staples perform statistically equivalent to the devices cleared under K142292, K993714 and K172052. 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*. Bacterial Endotoxins Test (BET) was performed on the Arthrex DynaNite Nitinol Staples utilizing the Kinetic Chromogenic Method in accordance with ANSI/AAMI ST72:2011/(R)2016, USP <161>, USP <85>, EP 2.6.14. The testing conducted demonstrates that the Arthrex DynaNite Nitinol Staples meet pyrogen limit specifications. Cytotoxicity, Sensitization, Irritation, Genotoxicity, Systemic Toxicity, Subchronic/Subacute Toxicity, Implantation and Material Characterization testing was conducted on the Arthrex DynaNite Nitinol Staples in accordance with ISO 10993-1:2018. Assessment of physical product attributes including product, design, size, and materials as well as the conditions of manufacture and packaging has determined that the Arthrex DynaNite Nitinol Staples do not introduce additional risks or concerns regarding sterilization and shelf-life.
Conclusion	The Arthrex DynaNite Nitinol Staples are substantially equivalent to the predicate devices in which the basic design features and intended uses are the same. Any differences between the proposed device and the predicate devices are considered minor and do not raise different questions concerning safety or effectiveness. The submitted mechanical testing data demonstrates that the Pull-out, Static Four-Point Bend, and Four-Point Bend Fatigue strength of the proposed device is substantially equivalent to that of the predicate devices for the desired indications. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex Inc. has determined that the proposed device is substantially equivalent to the currently marketed predicate devices.