June 29, 2020

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

Re: K200068
Trade/Device Name: Arthrex DynaNite K-Wire
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HTY
Dated: May 22, 2020
Received: May 26, 2020

Dear Ms. 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,

Charles Warner -S for

Colin O'Neill, M.B.E.
Acting Assistant Director
DHT6B: Division of Spinal 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200068

Device Name
Arthrex DynaNite K-Wire

Indications for Use *(Describe)*
The Arthrex DynaNite K-Wire is indicated for fixation of osteotomies and reconstruction of the lesser toes following correction procedure for hammertoe.

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 or 510(k) Statement

Date Prepared	May 22, 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 K-Wire
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Product Code	HTY
Classification Name	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Regulatory Class	II
Predicate Device	K132895: WMT Implantable K-Wires
Reference Devices	K052736: Arthrex K-Wire K172052: Arthrex DynaNite Nitinol Staple
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex DynaNite K-Wire.
Device Description	The Arthrex DynaNite K-Wire is a double tipped, unthreaded implantable Nickel Titanium (Nitinol) K-Wire consisting of two regions: a longer, superelastic end and a shorter, malleable end to allow fixation of bone fragments while being able to deform the protruding end. The Arthrex DynaNite K-Wire family ranges from 0.86 mm to 2.5 mm in diameter and is 5.91 inches in length. The Arthrex DynaNite K-Wire is sold sterile and is single-use.
Indications for Use	The Arthrex DynaNite K-Wire is indicated for fixation of osteotomies and reconstruction of the lesser toes following correction procedure for hammertoe.
Performance Data	Tensile (ASTM F2516), Reverse Bend (ISO 7801), Cantilever Static and Dynamic Fatigue Bend testing was conducted to demonstrate that the proposed Arthrex DynaNite K-Wire performs statistically equivalent to the predicate device cleared under K052736. Single Bend and Recovery, Transformation Temperature (ASTM F2082), and Cyclic Potentiodynamic Polarization Corrosion (ASTM F2129) testing was also conducted. 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 K-Wire 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 K-Wire meets pyrogen limit specifications.

	Cytotoxicity, Sensitization, Irritation, Genotoxicity, Systemic Toxicity, Subchronic/Subacute Toxicity, Implantation and Material Characterization testing was conducted on the Arthrex DynaNite K-Wire 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 K-Wire does not introduce additional risks or concerns regarding sterilization and shelf-life.
Conclusion	The Arthrex DynaNite K-Wire is substantially equivalent to the predicate device in which the basic design features and intended uses are the same. Any differences between the proposed device and the predicate device are considered minor and do not raise different questions concerning safety or effectiveness. The submitted mechanical testing data demonstrates that the tensile and fatigue strength of the proposed device is substantially equivalent to that of the predicate device 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 device.