May 3, 2019

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

Re: K190287
Trade/Device Name: Arthrex DynaNite® PIP (Hammertoe) Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: April 15, 2019
Received: April 17, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for CAPT Raquel Peat, PhD, MPH, USPHS
Director
Office of Health Technology 6
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)*
K190287

Device Name
Arthrex DynaNite® PIP (Hammertoe) Implant

Indications for Use *(Describe)*
The Arthrex DynaNite® PIP (Hammertoe) Implant is intended to stabilize and aid in the fixation of fractures, fusions, and osteotomies of the phalanges.

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	April 12, 2019
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Rebecca R. Homan Senior Regulatory Affairs Associate 1-239-643-5553, ext. 73429 rebecca.homan@arthrex.com
Name of Device	Arthrex DynaNite® PIP (Hammertoe) Implant
Common Name	Bone Fixation Fasteners
Product Code	HTY
Classification Name	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Regulatory Class	II
Predicate Device	K170326: dynaMX Intramedullary Implant (Primary Predicate) K960385: DePuy Sterile Kirschner Wires and Steinmann Pins (Reference Predicate) K172052: Arthrex DynaNite Nitinol Staple (Reference Predicate)
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex DynaNite PIP (Hammertoe) Implant.
Device Description	The Arthrex DynaNite PIP (Hammertoe) Implant is a Nickel Titanium (Nitinol) bone fixation device intended to be permanently implanted. The implant has a threaded end and a barbed end. The implant will be offered in 12mm, 14mm and 16 mm lengths, each available in straight and bent configurations. The implant is provided on a handled inserter and is sold as sterile, single-use.
Indications for Use	The Arthrex DynaNite PIP (Hammertoe) Implant is intended to stabilize and aid in the fixation of fractures, fusions, and osteotomies of the phalanges.
Performance Data	Barb Pull-out, Thread Pull-out, Static/Fatigue Cantilever Bend, Insertion Torque/Failure Torque, and Corrosion resistance testing were conduct to demonstrate that the Arthrex DynaNite PIP (Hammertoe) Implant performed statistically equivalent to the predicate device cleared under K960385. Barb Compression Force and Transformation Temperature tester were also conducted. Bacterial Endotoxins Test (BET) was performed on the Arthrex DynaNite PIP (Hammertoe) Implant utilizing the Kinetic Chromogenic Method in accordance with ANSI/AAMI ST72:2011/(R)2016, USP <161>, USP <85>, EP 2.6.14. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820. The testing conducted demonstrates that the Arthrex DynaNite PIP (Hammertoe) Implant meets pyrogen limit specifications.
Conclusion	The Arthrex DynaNite PIP (Hammertoe) Implant is 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 of safety or effectiveness. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex Inc. has determined that the Arthrex DynaNite PIP (Hammertoe) Implant is substantially equivalent to the currently marketed predicate device.