DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 9, 2015

Arthrex, Incorporated
Mr. David L. Rogers
Regulatory Affairs
1370 Creekside Boulevard
Naples, Florida 34108

Re: K143702
Trade/Device Name: Arthrex Blunt Tip Screws with FiberTape
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY, GAT
Dated: January 13, 2015
Received: January 14, 2015

Dear Mr. Rogers:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143702

Device Name

Arthrex Blunt Tip Screws with FiberTape

Indications for Use *(Describe)*

The Arthrex Blunt Tip Screws are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula. When used in conjunction with FiberTape, they can be used to treat patella fractures.

The Arthrex FiberTape suture products are intended for use in approximation and/or ligation of soft tissue, including use of allograft tissue for orthopedic surgeries. When used in conjunction with the Arthrex Blunt Tip Screws, FiberTape can be used to treat patella fractures.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

2.5 510K SUMMARY OF SAFETY AND EFFECTIVENESS

Date Summary Prepared	April 6, 2015
Manufacturer/ Distributor/ Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	David L Rogers Regulatory Affairs Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 71924 Fax: 239/598.5508 Email: david.rogers@arthrex.com
Trade Name	***Arthrex Blunt Tip Screws with FiberTape***
Common Name	Screw, Fixation, Suture
Product Code, Classification Name, CFR	HWC, GAT 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener 21 CFR 878.5000: Nonabsorbable Poly(ethylene) Terephthalate Surgical Suture
Predicate Device	*K103705: Arthrex Low Profile Screws* *K032245: Arthrex FiberTape Family* *K142442: Zimmer Magna-FX Cannulated Screw Fixation System*
Purpose of Submission	This **traditional 510(k)** premarket notification is submitted to obtain clearance for the ***Arthrex Blunt Tip Screws with FiberTape*** for internal bone fixation for bone fractures in the patella.
Device Description	The ***Arthrex Blunt Tip Screws with FiberTape*** is a construct that includes stainless steel, blunt tip, partially threaded, cannulated low profile screws and FiberTape.
Intended Use	The ***Arthrex Blunt Tip Screws*** are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula. When used in conjunction with ***FiberTape***, they can be used to treat patella fractures. The ***Arthrex FiberTape*** Family suture products are intended for use in approximation and/or ligation of soft tissue, including use of allograft tissue for orthopedic surgeries. When used in conjunction with the Arthrex Blunt Tip Screws, ***FiberTape*** can be used to treat patella fractures.
Substantial Equivalence Summary	The **Arthrex Blunt Tip Screws with FiberTape** is substantially equivalent to the predicate devices, in which the basic design features and intended uses are the same. Any differences between the ***Arthrex Blunt Tip Screws with FiberTape*** and the predicates are considered minor and do not raise questions concerning safety and effectiveness. Geometrical analysis demonstrates that the Arthrex Blunt Tip Screws are substantially equivalent to the Magna-FX Cannulated Screws. Based on the indication for use, technological characteristics, and the summary of data submitted, Arthrex, Inc. has determined that the ***Arthrex Blunt Tip Screws with FiberTape*** is substantially equivalent to currently marketed predicate devices.