



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

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

April 9, 2015

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

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement below.

## Indications for Use

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, calcaneus, 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.

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## 2.5 510K SUMMARY OF SAFETY AND EFFECTIVENESS

<b>Date Summary Prepared</b>	April 6, 2015
<b>Manufacturer/ Distributor/ Sponsor</b>	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
<b>510(k) Contact</b>	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: <a href="mailto:david.rogers@arthrex.com">david.rogers@arthrex.com</a>
<b>Trade Name</b>	<b>Arthrex Blunt Tip Screws with FiberTape</b>
<b>Common Name</b>	Screw, Fixation, Suture
<b>Product Code, Classification Name, CFR</b>	HWC, GAT 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener 21 CFR 878.5000: Nonabsorbable Poly(ethylene) Terephthalate Surgical Suture
<b>Predicate Device</b>	<i>K103705: Arthrex Low Profile Screws</i> <i>K032245: Arthrex FiberTape Family</i> <i>K142442: Zimmer Magna-FX Cannulated Screw Fixation System</i>
<b>Purpose of Submission</b>	This <b>traditional 510(k)</b> premarket notification is submitted to obtain clearance for the <b>Arthrex Blunt Tip Screws with FiberTape</b> for internal bone fixation for bone fractures in the patella.
<b>Device Description</b>	The <b>Arthrex Blunt Tip Screws with FiberTape</b> is a construct that includes stainless steel, blunt tip, partially threaded, cannulated low profile screws and FiberTape.
<b>Intended Use</b>	The <b>Arthrex Blunt Tip Screws</b> 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 <b>FiberTape</b> , they can be used to treat patella fractures.  The <b>Arthrex FiberTape</b> 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, <b>FiberTape</b> can be used to treat patella fractures.
<b>Substantial Equivalence Summary</b>	The <b>Arthrex Blunt Tip Screws with FiberTape</b> is substantially equivalent to the predicate devices, in which the basic design features and intended uses are the same. Any differences between the <b>Arthrex Blunt Tip Screws with FiberTape</b> 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 <b>Arthrex Blunt Tip Screws with FiberTape</b> is substantially equivalent to currently marketed predicate devices.