K090107

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510(k) Summary of Safety and Effectiveness

Manufacturer/ Distributor/ Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Sally Foust, RAC Regulatory Affairs Project Manager Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1251 Fax: 239/598.5508 Email: sfoust@arthrex.com
Trade Name	Mini TightRope
Common Name	Button / Anchor / Suture
Product Code - Classification Name	**HTN** – Single/multiple component metallic bone fixation appliances and accessories
Predicate Device	Mini TightRope Repair Kit, K061925 Mini TightRope FT Repair Kit, K071978 ACL RetroConstruction Button Kit, K031666
Device Description and Intended Use	The Mini TightRope is designed as either two metal buttons with a pre-threaded FiberWire suture or as one metal button, one bioabsorbable suture anchor with one pre-threaded FiberWire suture. The Arthrex Mini TightRope and Mini TightRope FT are intended as adjuncts in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as adjuncts in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting. Specifically, the Arthrex Mini TightRope and the Mini TightRope FT are intended to provide fixation during the healing process following: 1) Syndesmotic trauma, such as fixation of dorsal distal radioulnar ligament (DRUL) disruptions; 2) Tarsometatarsal (TMT) injury, such as fixation of foot soft tissue separations due to a Lisfranc injury (Midfoot Reconstruction); and 3) Hallux Valgus reconstruction (correction) by providing for the reduction of 1st metatarsal -2nd metatarsal intermetatarsal angle. The Arthrex Mini TightRope and the Mini TightRope FT, when used for fixation of bone-to-bone or soft-tissue-to-bone, are intended as fixation posts, distribution bridges, or for distributing suture tension over areas of ligament or tendon repair. Specifically, the Arthrex Mini TightRope and the Mini TightRope FT are indicated for Carpal

	Metacarpal (CMC) joint arthroplasty as an adjunct in the healing process of the reconstruction of the ligament at the base of the thumb metacarpal by providing stabilization between the base of the first and second metacarpal when the trapezium has been excised due to osteoarthritis.
Substantial Equivalence Summary	The Mini TightRope with expanded indications is substantially equivalent to the predicate Mini TightRope devices and the AC RetroConstruction Button Kit in which the basic features are identical and the intended uses are very similar. Any differences between the Mini TightRope with expanded indications and the predicate devices are considered minor and do not raise questions concerning safety and effectiveness. Based on the information submitted, Arthrex, Inc. has determined that the Mini TightRope with expanded indications is substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Arthrex, Inc.
% Ms. Sally Foust
Regulatory Affairs Project Manager
1370 Creekside Boulevard
Naples, Florida 34108

AUG 0 6 2009

Re: K090107
Trade/Device Name: Mini TightRope
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HTN, HWC
Dated: July 27, 2009
Received: July 29, 2009

Dear Ms. Foust:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number (if known: K090107

Device Name: Mini TightRope

Indications For Use:

The Arthrex Mini TightRope and Mini TightRope FT are intended as adjuncts in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as adjuncts in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

Specifically, the Arthrex Mini TightRope and the Mini TightRope FT are intended to provide fixation during the healing process following:

1) Syndesmotic trauma, such as fixation of dorsal distal radioulnar ligament (DRUL) disruptions;
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3) Hallux Valgus reconstruction (correction) by providing for the reduction of 1st metatarsal -2nd metatarsal intermetatarsal angle.

The Arthrex Mini TightRope and the Mini TightRope FT, when used for fixation of bone-to-bone or soft-tissue-to-bone, are intended as fixation posts, distribution bridges, or for distributing suture tension over areas of ligament or tendon repair. Specifically, the Arthrex Mini TightRope and the Mini TightRope FT are indicated for Carpal Metacarpal (CMC) joint arthroplasty as an adjunct in the healing process of the reconstruction of the ligament at the base of the thumb metacarpal by providing stabilization between the base of the first and second metacarpal when the trapezium has been excised due to osteoarthritis.

Prescription Use _X_ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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