Date Summary Prepared	29 JANUARY 2014
Manufacturer/ Distributor/ Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Nancy Hoft Regulatory Affairs Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 71113 Fax: 239/598.5508 Email: nancy.hoft@arthrex.com
Trade Name	Mini TightRope
Common Name	Button / Anchor / Suture
Product Code, Classification Name, CFR	**HTN** – Single/multiple component metallic bone fixation appliances and accessories - 888.3030
Predicate Device	Mini TightRope, **K090107**
Purpose of Submission	This **traditional 510(k)** premarket notification is submitted to introduce to the cleared Arthrex Mini TightRope devices, K090107: ▪ A second Carpal Metacarpal (CMC) joint indication of Hematoma Distraction Arthroplasty (HDA).
Device Description	The Mini TightRope devices are designed in two basic configurations: two metal buttons and a pre-threaded FiberWire suture and; one metal button, one bioabsorbable suture anchor.
Intended 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; 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 thumb metacarpal by providing stabilization between the base of the first and second metacarpals when the trapezium has been excised due to osteoarthritis. The Mini TightRope and Mini TightRope FT are also indicated for use as adjuncts in the suspension of the thumb metacarpal during the healing process of hematoma distraction arthroplasty by providing stabilization at the base of the first and second metacarpal when the trapezium has been excised due to osteoarthritis.
Substantial Equivalence Summary	The Arthrex Mini TightRope family of devices is substantially equivalent to the predicate devices, in which the basic design features and intended uses are the same. Any differences between the Arthrex Mini TightRope family of devices and the

	predicates are considered minor and do not raise questions concerning safety and effectiveness. The Mini-TightRope family of devices, when used as adjuncts in the suspension of the thumb metacarpal during the healing process, provides adequate stabilization for hematoma distraction arthroplasty (HDA) at the base of the first and second metacarpal when the trapezium has been excised due to osteoarthritis. The submitted mechanical testing data demonstrates that the shear and tensile strength of the predicate devices are adequate for the desired proposed indication. The submitted clinical literature review demonstrates the same. Based on the proposed indication for use, technological characteristics, and the summary of data submitted, Arthrex, Inc., has determined that the Arthrex Mini TightRope family of devices is substantially equivalent to the currently marketed predicate devices.

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

January 30, 2014

Arthrex, Incorporated
Ms. Nancy Hoft
Regulatory Affairs
1370 Creekside Boulevard
Naples, Florida 34108

Re: K133275
Trade/Device Name: Mini TightRopes
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HTN
Dated: November 6, 2013
Received: November 12, 2013

Dear Ms. Hoft:

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 Small Manufacturers, International and Consumer Assistance 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" (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 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

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

Enclosure

K133275

2.4 INDICATIONS FOR USE

Indications for Use

510(k) Number (if known):

Device Name: Mini TightRopes

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;
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 thumb metacarpal by providing stabilization between the base of the first and second metacarpals when the trapezium has been excised due to osteoarthritis. The Mini TightRope and Mini Tight Rope FT are also indicated for use as adjuncts in the suspension of the thumb metacarpal during the healing process of hematoma distraction arthroplasty by providing stabilization at the base of the first and second metacarpal when the trapezium has been excised due to osteoarthritis.

Prescription Use _✓_ 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)

PAGE 1 of 1

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices