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2.6 510K SUMMARY OF SAFETY AND EFFECTIVENESS

Date Summary Prepared	06 FEBRUARY 2014
Manufacturer/ Distributor/ Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Nancy Hoft Regulatory Affairs Specialist 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	**CMC 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, **K133275**
Purpose of Submission	This **special 510(k)** premarket notification is submitted to obtain clearance for the CMC Mini TightRope line extension.
Device Description	The Arthrex CMC Mini TightRope consists of two oblong stainless steel buttons and a single strand of #2 FiberWire.
Intended Use	The Arthrex CMC Mini TightRope, when used for fixation of bone-to-bone or soft-tissue-to-bone, is intended as a fixation post, distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. Specifically, the Arthrex CMC Mini TightRope is indicated for Carpal Metacarpal (CMC) joint arthroplasty as an adjunct 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 CMC Mini TightRope** is substantially equivalent to the Arthrex Implant System, Mini TightRope. Any differences between the CMC Mini TightRope and this predicate are considered minor and do not raise questions concerning safety and effectiveness. The proposed device, the Arthrex CMC Mini TightRope, is composed of two stainless steel oblong buttons and 1 strand of #2 FiberWire, which together form one construct consisting of two limbs of suture. The predicate device consists of two of the same constructs as that of the proposed device: four oblong stainless steel buttons and two strands of #2 FiberWire. The mechanical testing data demonstrated that the proposed device can withstand the tensile and shear forces in the hand during the healing period as they relate to the basic positions of the thumb during hand function. Based on the indication for use, technological characteristics, and the comparison to the predicate device, Arthrex, Inc. has determined that the **CMC Mini TightRope** is substantially equivalent to the currently marketed predicate device.

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

March 10, 2014

Arthrex, Inc.
Ms. Nancy Hoft
Regulatory Affairs Specialist
1370 Creekside Blvd.
Naples, Florida 34108-1945

Re: K140328
Trade/Device Name: CMC Mini TightRope
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: February 6, 2014
Received: February 10, 2014

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" (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 (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

2.5 INDICATIONS FOR USE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)* K140328

Device Name

CMC Mini TightRope

Indications for Use *(Describe)*

The Arthrex CMC Mini TightRope, when used for fixation of bone-to-bone or soft-tissue-to-bone, is intended as a fixation post, distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. Specifically, the Arthrex CMC Mini TightRope is indicated for Carpal Metacarpal (CMC) joint arthroplasty as an adjunct 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices

FORM FDA 3881 (9/13)

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