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JUN 28 2010

4 510(k) Summary of Safety and Effectiveness

Date	May 20, 2010
Manufacturer/Distributor /Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Geena Augustine Quality Engineer Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 2207 Fax: 239/566.5851 Email: geena.augustine@arthrex.com
Trade Name	*ACL TightRope*
Common Name	Pin, fixation, smooth Suture, Nonabsorbable, synthetic, polyethylene
Classification Name	**21 CFR 888.3040:** Smooth or threaded metallic bone fixation fastener **21 CFR 878.5000:** Nonabsorbable poly(ethylene terephthalate) surgical suture.
Product Code - Classification Name	**GAT** - Nonabsorbable poly(ethylene terephthalate) surgical suture. **HTY**- Smooth or threaded metallic bone fixation fastener.
Predicate Devices	*K062747*: Arthrex RETROBUTTON™ *K031666:* Arthrex Fiberwire® Button Repair Kit
Device Description and Intended Use	The ***ACL TightRope*** consists of an adjustable non-absorbable suture loop and titanium button. The ***ACL TightRope*** is to be used for fixation of bone to bone or soft tissue to bone, and is intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. Specifically, Arthrex will be offering this for Anterior Cruciate Ligament (ACL) Repair.
Substantial Equivalence Summary	The ***ACL TightRope*** is substantially equivalent to the predicate devices in which the intended uses is the same and basic features are very similar. Any differences between the ***ACL TightRope*** and the predicate devices are considered minor and do not raise questions concerning safety and effectiveness.

	The proposed device contains a titanium button and non-absorbable suture which are similar to the predicate devices. The proposed device contains an adjustable suture loop when compared to the predicate devices which contain constant loop lengths. From the mechanical testing completed the ultimate load and cyclic displacement are substantially equivalent for the proposed device when compared to the predicate devices. Based on the indication for use, technological characteristics and the comparison to the predicate device, Arthrex, Inc. has determined that the ***ACL TightRope*** 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 – WO66-0609
Silver Spring, MD 20993-0002

Arthrex, Inc.
c/o Ms. Geena Augustine
Quality Engineer
1370 Creekside Boulevard
Naples, Florida 34108-1945

JUN 23 2010

Re: K100652
Trade/Device Name: ACL TightRope
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY, GAT
Dated: May 21, 2010
Received: May 24, 2010

Dear Ms. Augustine:

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 such 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.

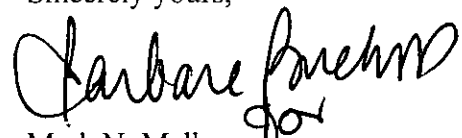
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); 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 (301) 796-7100 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

3 Indications for Use Form

Indications for Use

510(k) Number: K100652

Device Name: ***ACL TightRope***

The ***ACL TightRope*** is to be used for fixation of bone to bone or soft tissue to bone, and is intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. Specifically, Arthrex will be offering this for Anterior Cruciate Ligament (ACL) Repair.

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)

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Janita D. for MKM

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

510(k) Number K100652