DEC 19 2011

3 510(k) Summary of Safety and Effectiveness

Date Summary Prepared	October 4, 2011
Manufacturer/Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Christina Flores Regulatory Affairs Specialist Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1819 Fax: 239/598.5508 Email: Christina.flores@arthrex.com
Trade Name	ACL TightRope; ACL TightRope Double Bundle
Common Name	Pin, fixation, smooth Suture, Nonabsorbable, synthetic, polyethylene
Product Code -Classification Name *CFR*	**21 CFR 888.3040**: Smooth or threaded metallic bone fixation fastener HTY - Smooth or threaded metallic bone fixation fastener **21 CFR 878.5000:** Nonabsorbable poly(ethylene terephthalate) surgical suture GAT - Nonabsorbable poly(ethylene terephthalate) surgical suture
Predicate Device	*K100652*Arthrex ACL TightRope *K101837*Arthrex ACL TightRope Double Bundle *K110123*Arthrex PCL TightRope
Purpose of Submission	This **traditional 510(k)** premarket notification is submitted to obtain clearance for the addition of the PCL indication to the ACL TightRope and the ACL TightRope Double Bundle.
Device Description and Intended Use	The ***ACL TightRope*** consists of an adjustable nonabsorbable suture loop and titanium button. The ***ACL TightRope Double Bundle*** consists of nonabsorbable suture loops, titanium button, and a PEEK Femoral Wedge. The ***ACL TightRope*** and ***ACL TightRope Double Bundle*** 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) and Posterior Cruciate Ligament (PCL) Repair and Reconstruction.
Substantial Equivalence Summary	The ***ACL TightRope*** and ***ACL TightRope Double Bundle*** with expanded indications are substantially equivalent to the existing ACL TightRope and ACL TightRope Double Bundle as no changes have been made to the devices. The ***ACL TightRope*** and ***ACL TightRope Double Bundle*** with expanded indications are substantially equivalent to the PCL TightRope device in which the basic design features and intended uses are very similar. Any design differences between the subject devices (***ACL TightRope*** and ***ACL TightRope Double Bundle*** with expanded indications) to the PCL TightRope are considered minor and do not raise questions concerning safety and effectiveness. Bench testing was conducted to determine the tensile load to failure strength of the ACL TightRope devices. Based on the information submitted, Arthrex, Inc. has determined that the ACL TightRope and ACL TightRope Double Bundle with expanded indications are 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 Room –WO66-G609
Silver Spring, MD 20993-0002

Arthrex, Incorporated
% Ms. Christina Flores
Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, Florida 34108

DEC 19 2011

Re: K112990
Trade/Device Name: ACL TightRope and ACL Tightrope Double Bundle
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY, GAT
Dated: October 4, 2011
Received: October 6, 2011

Dear Ms. Flores:

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.

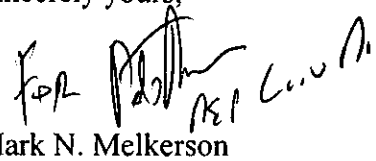
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

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

2 Indications for Use Form

510(k) Number: K112990

Device Name: **ACL TightRope and ACL Tightrope Double Bundle**

The ACL TightRope and ACL TightRope Double Bundle are to be used for fixation of bone to bone or soft tissue to bone, and are intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. Specifically, Arthrex will be offering these for ACL/PCL repair and reconstruction.

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)

1 of 1

for

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

510(k) Number K112990