APR 2 8 2011

K110123

1 510(k) Summary of Safety and Effectiveness

Date Summary Prepared	January 11, 2011
Manufacturer/Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Courtney Smith Regulatory Affairs Project Manager Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1720 Fax: 239/598.5508 Email: csmith@arthrex.com
Trade Name	***PCL TightRope***
Common Name	Fastener, fixation, nondegradable, soft tissue Suture, Nonabsorbable, synthetic, polyethylene
Product Code -Classification Name CFR	HTY, GAT **21 CFR 888.3040:** Smooth or threaded metallic bone fixation fastener **21 CFR 878.5000:** Nonabsorbable poly(ethylene terephthalate) surgical suture.
Predicate Device	*K071176*: Arthrex BioComposite Interference Screw *K100652*: Arthrex ACL TightRope
Purpose of Submission	This **traditional 510(k)** premarket notification is submitted to obtain clearance for the PCL TightRope.
Device Description and Intended Use	The proposed ***PCL TightRope*** consists of an adjustable non-absorbable suture loop, and 2 titanium buttons. The Arthrex *PCL TightRope* is intended 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. For example, ACL/PCL repair and reconstruction.
Substantial Equivalence Summary	The ***PCL TightRope*** is substantially equivalent to the previously cleared *Arthrex ACL TightRope*, in which the basic features and intended use are the same. It is substantially equivalent to the performance characteristics of the previously cleared *Arthrex BioComposite Interference Screw*, which is cleared for the same indications. Any differences between the ***PCL TightRope*** and the predicates are considered minor and do not raise questions concerning safety and effectiveness.

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	The proposed devices consist of a titanium button and non-absorbable suture which is substantially equivalent to the previously cleared *Arthrex ACL TightRope*. The submitted data demonstrated that the mechanical and biomechanical testing of the proposed devices is substantially equivalent to the ultimate load and cyclic displacement of the previously cleared *Arthrex BioComposite Interference Screw*. Based on the indication for use, technological characteristics, and the comparison with the predicate devices, Arthrex, Inc. has determined that the ***PCL TightRope*** is substantially equivalent to 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, Inc.
% Ms. Courtney Smith
Regulatory Affairs Associate
1370 Creekside Boulevard
Naples, Florida 34108-1945

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Re: K110123
Trade/Device Name: Arthrex PCL TightRope
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HTY, GAT
Dated: March 30, 2011
Received: April 5, 2011

Dear Ms. Smith:

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 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

1 Indications for Use Form

Indications for Use

510(k) Number (if known): K110123

Device Name: *Arthrex PCL TightRope*

Indications For Use:

The Arthrex *PCL TightRope* is intended 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. For example, ACL/PCL repair and reconstruction.

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)

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for M. Melkerson

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

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