### 510(k) Summary of Safety and Effectiveness

<table>
<thead>
<tr>
<th>Date Summary Prepared</th>
<th>October 4, 2011</th>
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| 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 | K100652Arthrex ACL TightRope  
K101837Arthrex ACL TightRope Double Bundle  
K110123Arthrex 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. 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 |

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

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" (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,

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: K122990

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

Michael [Signature]
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number: K122990