



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room –WO66-G609  
Silver Spring, MD 20993-0002

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

DEC 28 2010

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Re: K101837  
Trade/Device Name: 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, GAP  
Dated: December 20, 2010  
Received: December 22, 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

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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

DEC 2

**2 Indications for Use Form**

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Device Name: *ACL TightRope Double Bundle*

The *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) Repair.

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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*Neil H. Ogle for me*  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

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