DEC 1 2 2005

K052901
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VIII. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

ARTHREX TENSIONLOK™

MANUFACTURER / SPONSOR	Arthrex, Inc. 1370 Creekside Boulevard Naples, Florida 34108-1945
510(K) CONTACT:	Ann Waterhouse, RAC Regulatory Affairs Project Manager Telephone: (239) 643-5553 ext. 1179 FAX: (239) 598-5539
TRADE NAME:	TensionLok™
COMMON NAME:	Plate, Fixation, Bone
PRODUCT CODE / CLASSIFICATION NAME	HWC/ 21 CFR 888.3030 Plate, Fixation, Bone GAT/ 21 CFR 878.5000 Suture, Nonabsorbable Synthetic Polyethylene

PREDICATE DEVICE:
FiberWire Button Repair Kit: K031666

DEVICE DESCRIPTION AND INTENDED USE:
The Arthrex TensionLok™is a Titanium button per F136 available with pre-threaded FiberWire® suture.

The Arthrex TensionLok™ for fixation of bone to bone or soft tissue to bone is intended as a fixation post, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. Specifically, Arthrex will be offering this for ACL repair.

SUBSTANTIAL EQUIVALENCE SUMMARY
The Arthrex TensionLok™ is substantially equivalent to the predicate Arthrex FiberWire Button Repair Kit/ACL Retroconstruction™ Button Kit in which the basic features and intended uses are the same. Any differences between the Arthrex TensionLok™and the predicate Arthrex FiberWire Button Repair Kit/ACL Retroconstruction™ Button Kit are considered minor and do not raise questions concerning safety and effectiveness. Based on the information submitted, Arthrex, Inc. has determined that the TensionLok™ is substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 2005

Ms. Ann Waterhouse, RAC
Regulatory Affairs Project Manager
Arthrex Inc.
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K052901
Trade/Device Name: Arthrex TensionLok™
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, GAT
Dated: November 28, 2005
Received: November 29, 2005

Dear Ms. Waterhouse:

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 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

III. Indications for Use Form

510(k) Number (if known): K052901

Device Name: Arthrex TensionLok™

Indications for Use:

The Arthrex TensionLok™ for fixation of bone to bone or soft tissue to bone is intended as a fixation post, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. Specifically, Arthrex will be offering this for 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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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052901