JUL 1 1998

510(k) Summary

K981187

3/24/98

Company: Arthrex, Inc.
Address: 2885 S. Horseshoe Drive, Naples, FL 34104
Phone: (941) 643-5553
Fax: (941) 643-6218
Contact: Scott M. Durlacher
Director of Regulatory Affairs and Quality Assurance (ext. 117)

Trade Name: ACL Avulsion Lag Screw with Sheath
Common Name: Bone Screw
Classification: Screw, Fixation, Bone

Description:
A key to treating ACL avulsions is to determine whether the bony fragment is large enough to support internal fixation. The Arthrex Avulsion Lag Screw is specifically designed to allow rigid internal fixation of smaller bony fragments than has been possible with traditional screw designs. Because the avulsion screw is a cancellous bone screw, the risk of damage to the posterior neurovascular structures is minimized. If the fragment is too small, the transtibial suture technique should be used.

Intended Use:
The ACL Avulsion Lag Screw is intended for fixation of bone to bone. This product is intended for use in repairing Type IIIB ACL avulsions

Substantial Equivalence:
By definition, substantial equivalence means that a device has the same intended use and the same technological characteristics as the predicate device, or has the same intended use and different technological characteristics, but it can be demonstrated that the device is as safe and effective as the predicate device and does not raise different questions regarding safety and effectiveness from the predicate device.

A substantial equivalence comparison is given in the table below. In regards to the material, the titanium alloy 6AL-4V ELI used to manufacture the Arthrex ACL Avulsion Lag Screw meets the chemical and mechanical requirements in voluntary standards established by the American Society for Testing and Materials (ASTM F136).

Company	Device	Intended Use	Material
Arthrex	ACL Avulsion Lag Screw	Fixation of bone to bone – repairing Type IIIB ACL avulsions	Titanium alloy per ASTM F136
Acumed	2.7mm Extremity Bone Screw	Fixation of bone to bone – fracture and osteotomy fixation of the upper and lower extremities	Titanium alloy per ASTM F136
Aesculap	Titanium Alloy Bone Screw	Fixation of bone to bone – fixation of long and small bone fractures	Titanium alloy

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Scott M. Durlacher
Director of Regulatory Affairs and Quality Assurance
Arthrex, Inc.
2885 South Horseshoe Drive
Naples, Florida 34104

Re: K981187
ACL Avulsion Lag Screw with Sheath
Regulatory Class: II
Product Code: HWC
Dated: March 24, 1998
Received: April 2, 1998

Dear Mr. Durlacher:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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. Note that labeling or otherwise promoting a device for pedicular screw fixation/attachment would cause the device to be adulterated under 501(f)(1) of the Act. This device, if intended for use in pedicular screw fixation/attachment, would be found not substantially equivalent and would be a class III device under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing. Accordingly:

1. The package insert must prominently state that the device is intended for the specific use(s) described in the enclosure only; and

2. You may not label or in any way promote this device for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column. If this device is a screw with outer diameters of 3 mm - 10 mm and overall lengths of 10 mm - 75 mm inclusively, the

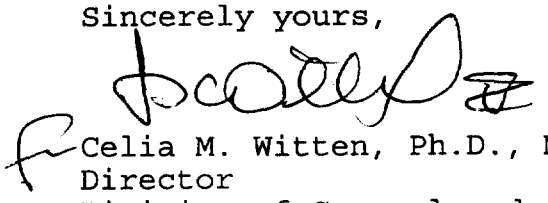
3. package insert must include the following statement, **"WARNING:** This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine." Any pedicular screw fixation/attachment to the cervical, thoracic or lumbar vertebral column of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulations under 21 CFR, Part 812. All users of the device for pedicular screw fixation/attachment must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conduct of the investigation.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Arthrex

K981187

Indications for Use

The **ACL Avulsion Lag Screw** is intended for fixation of bone to bone. This product is intended for use in repairing Type IIIB ACL avulsions.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981187

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