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510(k) Summary

5/7/97

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: Arthrex FASTak Suture Anchor
Common Name: Suture Anchor
Classification: Fastener, Fixation, Nondegradable, Soft Tissue (per 21 CFR 888.3040)

Description:
The FASTak is a threaded anchor with an eyelet for holding suture. The largest suture size used with the 11.7mm FASTak is a single strand of #2. Therefore, in order for the anchor to be effective, it must have a pull-out strength greater than the tensile strength of #2 suture (~ 15 lbs.). The pull-out strength of the FASTak in cortical bone, as well as cancellous, is at least 90 lbs. and thus provides an acceptable factor of safety.

The largest suture size used with the 7.5mm FASTak is a single strand of size 0. Therefore, in order for the anchor to be effective, it must have a pull-out strength greater than the tensile strength of size 0 suture (~ 10 lbs.). The pull-out strength of the FASTak in cortical bone as well as cancellous is at least 60 lbs. and thus provides an acceptable factor of safety.

In addition to fulfilling the requirements of a suture anchor, the FASTak eliminates the need for predrilling. In a single motion, the tissue is grasped, shifted and the FASTak inserted. The result is a technique which is both easier and more reproducible.

The FASTak is made of Titanium 6Al-4V alloy (ASTM F136-92). The biocompatibility of this alloy has been well documented.

Intended Use:
The FASTak Suture Anchor is intended for fixation of suture to bone. The 11.7mm FASTak is intended for the following uses:

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair

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Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction

Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction

Pelvis: Bladder Neck Suspension for female urinary incontinence due to urethral hyper mobility or intrinsic sphincter deficiency

The 7.5mm FASTak is intended for the same uses except Rotator Cuff Repair, Bankart Repair, and SLAP Lesion Repair

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. Although there are slight differences in design and pull-out strength between the various anchors, the critical value is the tensile strength of the suture. Since the pull-out strength of the FASTak is greater than the tensile strength of the supplied suture, the suture will clearly fail prior to the anchor pulling out.

Product	Indications	Pull-Out (lbs.)*		Suture Size
		Cancellous	Cortical	
FASTak (11.7mm)	**same**	**95**	**91**	**2**
Mitek GII	same	105**	43**	2
Statak 3.5	same	100	30	2
Questus 3.5	same	95	104	0, 2
Mainstay 3.5	same	unknown	unknown	0
PeBA C	same	129	143	unknown
FASTak (7.5mm)	**same**	**71 *****	**68 *****	**0**
Statak 2.5	same	65	37	0
Questus 2.5	same	35	unknown	2-0, 0, 2
Mainstay 2.7	same	unknown	unknown	2-0

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Contraindications

1. Surgeries other than those indicated.
2. Insufficient quantity or quality of bone.
3. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
4. Active infection.
5. Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
6. Pelvis: patients planning future pregnancies.
7. Pelvis: renal insufficiency and upper urinary tract relative obstruction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUL 30 1997

Re: K971723
FASTak Suture Anchor
Regulatory Class: II
Product Code: MBI
Dated: May 7, 1997
Received: May 9, 1997

Dear Mr. Durlacher:

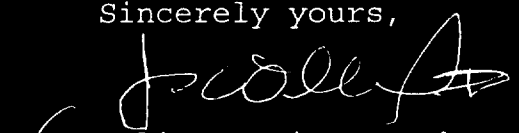
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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. 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 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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for 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

K971723

Arthrex

Indications for Use

The **FASTak Suture Anchor (11.7mm)** is intended for fixation of suture to bone. This product is intended for the following indications:

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair
Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis
Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction
Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligamant Reconstruction
Pelvis: Bladder Neck Suspension for female urinary incontinence due to urethral hyper mobility or intrinsic sphincter deficiency

The **FASTak Suture Anchor (7.5mm)** is intended for fixation of suture to bone. This product is intended for the following indications:

Shoulder: Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair
Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis
Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction
Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligamant Reconstruction
Pelvis: Bladder Neck Suspension for female urinary incontinence due to urethral hyper mobility or intrinsic sphincter deficiency

PRESCRIPTION USE: X

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971723

Arthrex Inc. • 2885 South Horseshoe Drive • Naples, Florida 34104 • Tel: (800)933-7001 or (941)643-5553 • Fax: (941)643-6218