1 510(k) Summary of Safety and Effectiveness

Date Summary Prepared	January 17, 2012
Purpose of Submission	To obtain clearance of the ***Arthrex Knotless SutureTak Anchor*** devices.
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	***Knotless SutureTak Anchor***
Common Name	fastener, fixation, nondegradable, soft tissue
Product Code - Classification Name	MBI - 21 CFR 888.3040 fastener, fixation, nondegradable, soft tissue HWC - 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener GAT - 21 CFR 878.5000: Nonabsorbable poly(ethylene terephthalate) surgical suture
Predicate Devices	*K061863 Arthrex 3 mm PEEK SutureTak*
Device Description and Intended Use	The ***Arthrex Knotless SutureTak Anchor*** is a tap-in ribbed suture anchor comprised of PEEK material and preloaded with UHMWPE looped suture and assembled to an insertion device. The proposed anchor is being offered in a 3 mm diameter. The ***Arthrex Knotless SutureTak Anchor*** is intended to be used for suture or soft tissue fixation to bone in shoulder, foot/ankle, knee, hand/wrist, elbow, and hip. These indications are identical to those cleared in K061863 with the exception of the removal of the Skull and Pelvis indications. The Arthrex Knotless SutureTak Anchor is intended to be used for suture or tissue fixation in the foot, ankle, knee, hand, wrist, elbow, shoulder, and hip. Specific indications are listed below: *Elbow*: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction *Shoulder*: Rotator Cuff Repairs, Bankart Repair, SLAP

		Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
	Hand/Wrist:	Scapholunate Ligament Reconstruction, Carpal Ligament Reconstructions, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP joints for all digits, Digital Tendon Transfers
	Foot/Ankle:	Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, Digital Tendon Transfers, Mid-foot Reconstruction
	Knee:	Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis
	Hip:	Capsular Repair, Acetabular Labral repair
Substantial Equivalence Summary	The ***Arthrex Knotless SutureTak Anchor*** is substantially equivalent to the predicate devices in which the basic features and intended uses are the same. Any differences between the *Knotless SutureTak Anchor* and the predicates are considered minor and do not raise questions concerning safety and effectiveness. The mechanical testing demonstrates that the proposed device meets or exceeds the established minimum acceptance criteria for tensile (pull-out) strength for the desired indications. Based on the indication for use, technological characteristics, and summary of data submitted, Arthrex, Inc. has determined that the ***Arthrex Knotless SutureTak Anchor*** is substantially equivalent to currently marketed predicate devices.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

FEB 17 2012

Arthrex, Inc.
% Ms. Christina Flores
1370 Creekside Boulevard
Naples, FL 34108-1945

Re: K120155
Trade/Device Name: Arthrex Knotless SutureTak Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI, HWC, GAT
Dated: January 17th, 2012
Received: January 18th, 2012

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. 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 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.
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,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3 Indications for Use Form

Indications for Use

510(k) Number (if known): K120155

Device Name: *Arthrex Knotless SutureTak Anchor*

Indications For Use:

The Arthrex Knotless SutureTak Anchor is intended to be used for suture or tissue fixation in the foot, ankle, knee, hand, wrist, elbow, shoulder, and hip. Specific indications are listed below:

Elbow:	Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction
Shoulder:	Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
Hand/Wrist:	Scapholunate Ligament Reconstruction, Carpal Ligament Reconstructions, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP, and MCP joints for all digits, Digital Tendon Transfers
Foot/Ankle:	Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, Digital Tendon Transfers, Mid-foot Reconstruction
Knee:	Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis
Hip:	Capsular Repair, Acetabular Labral 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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120155