DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Arthrex Inc.
% Ms. Nancy Hoft
Regulatory Affairs Associate
1370 Creekside Boulevard
Naples, Florida 34108

JAN 23 2009

Rcvd 1/30/09.
lg

Re: K082810
Trade/Device Name: Bio-Composite Suture Anchors, Expansion of Indications to include Hip
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MAI, HWC
Dated: January 20, 2009
Received: January 21, 2009

Dear Ms. Hoft:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

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

Enclosure

Indications for Use

510(k) Number: K082810

Device Name: **Arthrex Bio-Composite PushLock™**

The **Arthrex Bio-Composite PushLock™** is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, hip, and pelvis in the following procedures:

Shoulder: Rotator Cuff Repairs, 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, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair, Bunionectomy.

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 or Radial Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction.

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

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

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 General, Restorative, and Neurological Devices

510(k) Number K082810

3 Indications for Use Form

Indications for Use

510(k) Number: K082810

Device Name: **Arthrex Bio-Composite Corkscrew®**

The **Arthrex Bio-Composite Corkscrew** is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, hip, knee, hand/wrist, elbow, and pelvis in, but not limited to, the following procedures:

Shoulder: Rotator Cuff Repairs, 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, Mid-foot reconstruction, Metatarsal Ligament Repair/Tendon Repair, Bunionectomy.

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

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

Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial collateral Ligament Reconstruction, Lateral Epicondylitis Repair.

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

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)

PAGE 1 of 3

Indications for Use

510(k) Number: K082810

Device Name: **Arthrex Bio-Composite Tak**

The **Arthrex Bio-Composite Tak™** is intended to be used for suture or tissue fixation in the foot, ankle, knee, hip, hand, wrist, shoulder, elbow, and in select maxillofacial applications. Specific indications are listed below and are size appropriate per patient needs:

Skull: Stabilization and fixation of oral cranio-maxillofacial skeletal bone, mandible and maxillofacial bones, Lateral Canthoplasty, Repair of Nasal Vestibular Stenosis, Brow Lift, Temporomandibular Joint (TMJ) reconstruction, Soft tissue attachment to the parietal temporal ridge, frontal, zygoma, and periorbital bones of the skull.

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 Reconstruction, 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.

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

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)

May 4, 2021

To Whom This May Concern:

In accordance with the regulatory criteria in 21 CFR 807.81(a)(3) and FDA's Guidance *Deciding When to Submit a 510(k) for a Change to an Existing Device*, the differences between the devices cleared via K082810 Arthrex Bio-Composite Suture Anchors and the new devices (AR-8934BCST Suture Anchor, BioComposite SutureTak with 1.3 mm White/Blue SutureTape with two Tapered Needles and AR-8934BCST-2 Suture Anchor, BioComposite SutureTak Double Loaded with one 0.9 mm Whilte/Blue SutureTape and one 0.9 mm White SutureTape with four Tapered Needles) do not meet the threshold for requiring a new premarket notification. Therefore, the new devices (AR-8934BCST Suture Anchor, BioComposite SutureTak with 1.3 mm White/Blue SutureTape with two Tapered Needles and AR-8934BCST-2 Suture Anchor, BioComposite SutureTak Double Loaded with one 0.9 mm Whilte/Blue SutureTape and one 0.9 mm White SutureTape with four Tapered Needles) are considered cleared via K082810.

Sincerely,

Rebecca R. Homan
Senior Regulatory Affairs Specialist
Arthrex, Inc.