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3 510(k) Summary of Safety and Effectiveness

Date Summary Prepared	January 6, 2011
Manufacturer/Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Sally Foust, RAC Regulatory Affairs Project Manager Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1251 Fax: 239/598.5508 Email: sfoust@arthrex.com Courtney Smith Regulatory Affairs Project Manager Telephone: 239/643.5553, ext. 1720 Fax: 239/598.5508 Email: csmith@arthrex.com
Trade Name	***SwiveLock Anchors***
Common Name	Suture Anchor
Product Code -Classification Name CFR	HWC, MAI 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener. 21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories.
Predicate Device	*K082810*: Arthrex BioComposite Suture Anchors *K061863:* Arthrex PushLock, Tak and Corkscrew Suture Anchors *K051726:* Arthrex Tenodesis Family
Device Description and Intended Use	The ***SwiveLock Anchor*** is a two-component, knotless suture anchor comprised of an eyelet and a hollow anchor body. The ***SwiveLock Anchor*** is pre-mounted on a driver with the anchor body and eyelet physically separated on the driver shaft. FiberWire suture may also be provided with the device. The Arthrex ***SwiveLock Anchor*** is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, hip, and pelvis in many

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	procedures. Refer to the *Indications For Use Form* for specific indications for use.
Substantial Equivalence Summary	The ***Arthrex SwiveLock Anchors*** are substantially equivalent to the **Arthrex BioComposite Suture Anchors, Arthrex PushLock, Tak and Corkscrew Suture Anchors,** and **Arthrex Tenodesis Family** predicates, in which the basic features and intended uses are the same. Any differences between the *SwiveLock Anchors* and the predicates are considered minor and do not raise questions concerning safety and effectiveness. The proposed devices are composed of Bio, BioComposite, Peek, and Titanium materials that are substantially equivalent to the predicate devices. The submitted 26-week degradation data, mechanical pull-out (tensile) testing data, insertion testing data, animal testing (including histology, *in-vivo* pull-out and *in-vivo* imaging) data demonstrated that the proposed devices are substantially equivalent to the pull-out forces of the predicate devices and that there are no new issues of safety and effectiveness. Based on the indication for use, technological characteristics, degradation testing, mechanical pull-out testing, insertion testing, animal testing (including histology, *in-vivo* pull-out and *in-vivo* imaging) and design comparison to the predicate devices, Arthrex, Inc. has determined that the ***SwiveLock Anchors*** are substantially equivalent to currently marketed predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Arthrex, Inc.
% Ms. Sally Foust
Regulatory Affairs Project Manager
1370 Creekside Boulevard
Naples, Florida 34108-1945

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Re: K101823
Trade/Device Name: Arthrex Swivelock Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MAI, HWC
Dated: January 5, 2011
Received: January 6, 2011

Dear Ms. Foust:

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 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,

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

Enclosure

2 Indications for Use Form

Indications for Use

510(k) Number (if known): K101823

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Device Name: ***Arthrex SwiveLock Anchors***

Indications For Use:

The **Arthrex *SwiveLock Anchors*** are intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and hip 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.
Hip:	Capsular Repair, acetabular labral repair

Prescription Use _✓_ 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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for M. Melkerson

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

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