DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 4, 2017

Arthrex Inc.
Mr. David L. Rogers
Project Manager, Regulatory Affairs
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K171141
Trade/Device Name: Arthrex SwiveLock Anchors
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI, MBI
Dated: April 14, 2017
Received: April 18, 2017

Dear Mr. Rogers:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171141

Device Name
Arthrex SwiveLock Anchors

Indications for Use *(Describe)*
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 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, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair and Bunionectomy.

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, and Illiotibial Band Tenodesis. Secondary fixation of ACL/PCL reconstruction or repair (4.75 – 5.5 SwiveLock only).

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary: K171141

Date Prepared	April 14, 2017
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	David L Rogers Project Manager, Regulatory Affairs 1-239-643-5553, ext. 71924 david.rogers@arthrex.com
Name of Device	Arthrex SwiveLock Anchors
Common Name	Suture Anchor
Product Code	MAI, MBI
Classification Name	21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class	II
Predicate Device	K151342: Arthrex SwiveLock Anchors
Purpose of Submission	This Special 510(k) premarket notification is submitted to obtain clearance for the modification to the eyelet of the Arthrex SwiveLock Suture Anchors cleared under K151342.
Device Description	The Arthrex SwiveLock Anchor is a two-component, knotless suture anchor composed 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. Arthrex suture may also be provided with the device.
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 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, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair and Bunionectomy. • Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, and Illiotibial Band Tenodesis. Secondary fixation of ACL/PCL reconstruction or repair (4.75 – 5.5 SwiveLock only). • Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or 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.
Performance Data	Pull-out, compressive load, and insertion mode of failure testing was performed to demonstrate that the SwiveLock Anchors with the proposed modified eyelet are substantially equivalent to the predicate. Bacterial endotoxin per EP 2.6.14/USP <85> was conducted to demonstrate that the device meets pyrogen limit specifications.

Conclusion	The Arthrex SwiveLock Anchors are substantially equivalent to the predicate device in which the basic design features and intended uses are the same. Any differences between the proposed device and the predicate device are considered minor and do not raise questions concerning safety or effectiveness. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex Inc. has determined that the proposed device is substantially equivalent to the currently marketed predicate device.