



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Arthrex, Incorporated
Ms. Laura Medlin
Regulatory Affairs Associate
1370 Creekside Boulevard
Naples, Florida 34108-1945

August 20, 2015

Re: K150648

Trade/Device Name: Arthrex DX SwiveLock SL with Forket Eyelet 3.5 x 8.5mm, Arthrex DX SwiveLock Suture Anchor, 3.5 x 13.5mm

Regulation Number: 21 CFR 888.3040

Regulation Name: Smooth or threaded metallic bone fixation fastener

Regulatory Class: Class II

Product Code: MBI

Dated: March 9, 2015

Received: March 12, 2015

Dear Ms. Medlin:

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 yours,

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)
K150648

Device Name
Arthrex DX SwiveLock SL with Forked Eyelet 3.5 x 8.5mm

Indications for Use (Describe)

The Arthrex MicroSuture Anchors are intended to be used for suture or tissue fixation in the foot/ankle, knee, hand/wrist, elbow, and shoulder. Specific indications for use are listed below:

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

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

Hand/Wrist: Scapholunate 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, Carpal Ligament Reconstruction and Carpometacarpal Joint Arthroplasty (basal thumb joint arthroplasty)

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

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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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)
K150648

Device Name
Arthrex DX SwiveLock Suture Anchor, 3.5 x 13.5mm

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 Repairs, Bankart Repairs, 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.

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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2.5 510K SUMMARY OF SAFETY AND EFFECTIVENESS

Date Summary Prepared	August 10, 2015
Manufacturer/ Distributor/ Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Laura Medlin Regulatory Affairs Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 72005 Fax: 239/598.5508 Email: laura.medlin@arthrex.com
Trade Name	Arthrex DX SwiveLock SL with Forked Eyelet, 3.5 x 8.5mm Arthrex DX SwiveLock Suture Anchor, 3.5 x 13.5mm
Common Name	Suture Anchor
Product Code, Classification Name, CFR	MBI 21 CFR 888.3030: Smooth or threaded metallic bone fixation fastener
Predicate Device	<i>K101823: Arthrex SwiveLock Anchors</i> <i>K112237: Arthrex MicroSuture Anchors</i>
Purpose of Submission	This traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex DX SwiveLock SL with Forked Eyelet, 3.5 x 8.5mm and Arthrex DX SwiveLock Suture Anchor, 3.5 x 13.5mm . This bundled submission has been converted from a Special to Traditional 510(k) premarket notification as Arthrex has chosen to establish substantial equivalence by means of two predicate devices previously cleared under the auspices of K101823 and K112237, respectively.
Device Description	The Arthrex DX SwiveLock SL with Forked Eyelet, 3.5 x 8.5mm and Arthrex DX SwiveLock Suture Anchor, 3.5 x 13.5mm share the same design features, materials, and intended use as the predicates. The anchors are composed of Polyetheretherketone (PEEK) and are preloaded on a driver with nonabsorbable suture. The anchors are provided in a 3.5mm diameter and feature lengths of 8.5 and 13.5mm, respectively.
Intended Use	The Arthrex DX SwiveLock SL with Forked Eyelet, 3.5 x 8.5mm is intended to be used for suture or tissue fixation in the foot/ankle, knee, hand/wrist, elbow, and shoulder. Specific indications for use are listed below: Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction Hand/Wrist: Scapholunate 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, Carpal Ligament Reconstruction and Carpometacarpal Joint Arthroplasty (basal thumb joint arthroplasty) 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

The **Arthrex DX SwiveLock Suture Anchor, 3.5 x 13.5mm** is 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 Repairs, 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

**Substantial
Equivalence Summary**

The **Arthrex DX SwiveLock SL with Forked Eyelet, 3.5 x 8.5mm** and **Arthrex DX SwiveLock Suture Anchor, 3.5 x 13.5mm** are substantially equivalent to the predicate devices, in which the basic design features and intended uses are the same.

The predicate *Arthrex MicroSuture Anchors (K112237)* are composed of titanium or PLDLA/βTCP and are provided pre-loaded on a driver with suture. The predicate anchors range from 2.2 – 2.7mm in diameter and 4.0 – 7.0mm in length. The predicate *Arthrex SwiveLock Anchors (K101823)* bodies are fully threaded, fully cannulated and may be vented or non-vented. The SwiveLock Anchor eyelet may feature an open or closed design. SwiveLock components, anchor bodies and eyelets are manufactured from various materials and are sold in different component/material combinations. The predicate devices are provided pre-mounted on a driver with the anchor body and eyelet physically separated on a driver shaft. FiberWire® Suture may also be packaged with the sterile *Arthrex SwiveLock Anchors*.

Similar to the predicate product offering, the devices subject of this 510(k) premarket notification are featured in a 3.5mm diameter and lengths of 8.5 and 13.5mm, respectively. Identical to the predicate anchors, the **Arthrex DX SwiveLock SL with Forked Eyelet, 3.5 x 8.5mm** and **Arthrex DX SwiveLock Suture Anchor, 3.5 x 13.5mm** are manufactured from Polyetheretherketone (PEEK), may be provided vented or non-vented, and feature an open or closed eyelet design. The **Arthrex DX SwiveLock SL with Forked Eyelet, 3.5 x 8.5mm** and **Arthrex DX SwiveLock Suture Anchor, 3.5 x 13.5mm** are pre-mounted on a driver with the anchor body and eyelet physically separated on a driver shaft. The product is packaged sterile with FiberWire™ Suture. Any differences between the **Arthrex DX SwiveLock SL with Forked Eyelet, 3.5 x 8.5mm** and **Arthrex DX SwiveLock Suture Anchor, 3.5 x 13.5mm** and the predicates are considered minor and do not raise questions concerning safety and effectiveness.

The submitted mechanical testing data demonstrates that the pull-out strength and torque to failure of the proposed devices meets or exceeds that of the predicate devices for the desired indications.

Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex, Inc. has determined that the **Arthrex DX SwiveLock SL**

with Forked Eyelet, 3.5 x 8.5mm and *Arthrex DX SwiveLock Suture Anchor, 3.5 x 13.5mm* are substantially equivalent to currently marketed predicate devices.
