DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 2, 2015

Arthrex, Incorporated
Mr. David Rogers
Regulatory Affairs Associate
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K143745
Trade/Device Name: Arthrex Corkscrew and SwiveLock Suture Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: May 12, 2015
Received: May 14, 2015

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 yours,

Lori A. Wiggins -S

for
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)*

K143745

Device Name
Arthrex Corkscrew Suture Anchors

Indications for Use *(Describe)*

The Arthrex Corkscrew suture anchors are intended to be used for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, hip, knee, hand/wrist, and elbow 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: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, and Illiotibial Band Tenodesis.

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, gluteus medius 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.**

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:

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

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)*

K143745

Device Name
Arthrex SwiveLock Suture 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.

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, gluteus medius 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)

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## 510K SUMMARY OF SAFETY AND EFFECTIVENESS

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| ***Date Summary Prepared*** | June 30, 2015 |
| ***Manufacturer/ Distributor/ Sponsor*** | Arthrex, Inc.<br>1370 Creekside Boulevard<br>Naples, FL 34108-1945 USA |
| ***510(k) Contact*** | David L Rogers<br>Regulatory Affairs<br>Arthrex, Inc.<br>1370 Creekside Boulevard<br>Naples, FL 34108-1945 USA<br>Telephone: 239/643.5553, ext. 71924<br>Fax: 239/598.5508<br>Email: david.rogers@arthrex.com |
| ***Trade Name*** | ***Arthrex Corkscrew and SwiveLock Suture Anchors*** |
| ***Common Name*** | Suture Anchor |
| ***Product Code, Classification Name, CFR*** | MBI<br>21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener |
| ***Predicate Device*** | *K113294: HEALICOIL PK Suture Anchor*<br>*K101823: Arthrex SwiveLock Anchors*<br>*K061863: Arthrex Corkscrew, Corkscrew FT, Bio-Corkscrew, and Bio Corkscrew FT Suture Anchors* |
| ***Purpose of Submission*** | This **traditional 510(k)** premarket notification is submitted to obtain clearance for the ***Arthrex Corkscrew and SwiveLock Suture Anchors*** for gluteus medius repair in the hip. |
| ***Device Description*** | The ***Arthrex Corkscrew and SwiveLock Suture Anchors*** consist of cannulated anchors manufactured from polyetheretherketone (PEEK) or Titanium with an integral or separate eyelet. They are pre-loaded on a handled inserter. Suture, with or without needles, and a suture threader may also be provided. |
| ***Intended Use*** | The **Arthrex Corkscrew** suture anchors are intended to be used for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, hip, knee, hand/wrist, and elbow in the following procedures:<br>• Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.<br>• Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair and Bunionectomy.<br>• Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, and Illiotibial Band Tenodesis.<br>• Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction.<br>• Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis repair.<br>• Hip: Capsular repair, acetabular labral repair, gluteus medius repair.<br><br>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:<br>• Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction.<br>• Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair/Tendon Repair and Bunionectomy.<br>• Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament |

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| | Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, and Illiotibial Band Tenodesis.<br>• Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction.<br>• Elbow: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis repair.<br>• Hip: Capsular repair, acetabular labral repair, gluteus medius repair. |
| ***Substantial Equivalence Summary*** | The **Arthrex Corkscrew and SwiveLock Suture Anchors** is substantially equivalent to the predicate devices, in which the basic design features and intended uses are the same. Any differences between the ***Arthrex Corkscrew and SwiveLock Suture Anchors*** and the predicates are considered minor and do not raise questions concerning safety and effectiveness.<br><br>The submitted insertion testing, static pull-out testing, fatigue testing, and suture abrasion testing data demonstrates that the proposed devices are substantially equivalent to the predicates.<br><br>Based on the indication for use, technological characteristics, and the summary of data submitted, Arthrex, Inc. has determined that the ***Arthrex Corkscrew and SwiveLock Suture Anchors*** is substantially equivalent to currently marketed predicate devices. |