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

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

February 23, 2016

Re: K151092
Trade/Device Name: Arthrex Short 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: January 15, 2016
Received: January 19, 2016

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 Parts 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" (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 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)*
K151092

Device Name
Arthrex Short Suture Anchors

Indications for Use *(Describe)*
The Arthrex Short Suture Anchors are intended to be used for suture (soft tissue) fixation to bone in the hip. Specifically, 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.

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

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2.6 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Date Summary Prepared	April 21, 2015
Manufacturer/Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	David L Rogers Regulatory Affairs Associate Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 71924 Fax: 239/598.5508 Email: david.rogers@Arthrex.com
Trade Name	**Arthrex Short Suture Anchors**
Common Name	Suture Anchor
Product Code -Classification Name ***CFR***	MBI 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Predicate Device	*K140855: Arthrex SutureTak Suture Anchors*
Reference Predicate Device	*K110473: Pivot Nanotak Suture Anchor*
Purpose of Submission	This Special 510(k) premarket notification is intended to address the ***Arthrex Short Suture Anchors*** as a line extension to the Arthrex SutureTak Suture Anchors, K140855. The intended use, material, and fundamental technological characteristics of the proposed ***Arthrex Short Suture Anchors*** are substantially equivalent to the predicate.
Device Description	The ***Arthrex Short Suture Anchors*** share the same design features, materials, and intended use as the predicate. The anchors consist of cannulated anchors with an integral or separate eyelet. They are pre-loaded on a handle inserter. Suture, with or without needles, and a suture threader may be provided. The anchors are made from polyetheretherketone (PEEK) and range from 2.0mm – 2.4mm in diameter and 8.6 – 9.0mm in length (including eyelet).
Indications For Use	*The **Arthrex Short Suture Anchors** are intended to be used for suture (soft tissue) fixation to bone in the hip.*

	Specifically, acetabular labral repair.
Substantial Equivalence Summary	The ***Arthrex Short Suture Anchors*** are substantially equivalent to the predicate devices in which the basic design features and intended uses are the same. Any differences between the ***Arthrex Short Suture Anchors*** and the predicates are considered minor and do not raise questions concerning safety and effectiveness. The submitted tensile testing data demonstrates that the performance of the proposed devices meets or exceeds the predicate device 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 Short Suture Anchors*** are substantially equivalent to the predicate.