JAN 30 2014

510(K) SUMMARY

Date Summary Prepared	December 31, 2013
Manufacturer/Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Courtney Smith Regulatory Affairs Manager Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1720 Fax: 239/598.5508 Email: csmith@arthrex.com
Trade Name	***Arthrex BioSuture***
Common Name	Suture
Product Code -Classification Name ***CFR***	GAT Nonabsorbable poly(ethylene terephthalate) surgical suture 21 CFR 878.5000
Predicate Device	K112899: Arthrex BioSuture
Purpose of Submission	This special 510(k) premarket notification is submitted to extend the shelf-life of the Arthrex BioSuture.
Device Description	The Arthrex Bio-Suture is a dyed or non-dyed braided polyester suture construct coated with type 1 bovine collagen. The suture construct is made of UHMWPE and polyester braided over a UHMWPE core. The suture tape construct is a flat suture construct composed of UHMWPE and polyester yarns braided over a FiberWire suture core and UHMWPE yarns. Arthrex Bio-Suture strands that are dyed black are made of nylon. The suture ends are stiffened with cyanoacrylate. The Arthrex Bio-Suture will be supplied in pre-cut lengths with or without various swaged needles. The Arthrex Bio-

	Suture constructs meet USP standards for suture, except for diameter.
Intended Use	The Arthrex BioSuture is intended for soft tissue approximation and or ligation. These sutures may be incorporated, as components, into surgeries where constructs, including those with allograft or autograft tissues, are used for repair.
Substantial Equivalence Summary	The Arthrex BioSuture is identical to the predicate devices, in which the basic design features, materials, and intended uses are the same. The extension of the shelf life is the only change presented in this submission. The real-time stability testing (Ultimate Load and Anchor Pullout) data demonstrates that the extended shelf life does not affect the performance of the device. Based on the indication for use, technological characteristics, and the summary of data submitted, Arthrex, Inc. has determined that the BioSuture is substantially equivalent to currently marketed predicate devices.

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

January 30, 2014

Arthrex Incorporated
Ms. Courtney Smith
Regulatory Affairs Manager
1370 Creekside Boulevard
Naples, Florida 34108

Re: K140019
Trade/Device Name: Arthrex BioSuture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: Class II
Product Code: GAT
Dated: December 31, 2013
Received: January 3, 2014

Dear Ms. Smith:

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 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. 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical 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 on last page.

510(k) Number *(if known)*
K140019

Device Name
Arthrex BioSuture

Indications for Use *(Describe)*

The Arthrex BioSuture is intended for soft tissue approximation and or ligation. These sutures may be incorporated, as components, into surgeries where constructs, including those with allograft or autograft tissues, are used for 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

David Krause -S