APR - 6 2012 K112899

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4 510(k) Summary of Safety and Effectiveness

Date Summary Prepared	September 30, 2011
Purpose of Submission	To obtain clearance to distribute new suture devices, ***Arthrex Bio-Suture***
Manufacturer/Distributor /Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Sally Foust, RAC Regulatory Affairs Project Manager Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1251, and Fax: 239/598-5508 Email: sfoust@arthrex.com
Trade Name	***Arthrex Bio-Suture:*** *Bio-FiberWire, Bio-TigerWire, Bio-FiberLoop, Bio-TigerLoop, Bio-FiberTape, and Bio-TigerTape*
Common Name	Suture
Product Code - Classification Name	878.5000 -GAT – Nonabsorbable poly(ethylene terephthalate) surgical suture
Predicate Devices	*Arthrex Graft Suturing Kit* (K041553) *Arthrex BioWire (K091018)*
Device Description and Intended Use	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. The ***Arthrex Bio-Suture*** is intended for use in 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 Bio-Suture*** is substantially equivalent to the predicate devices in which the material, basic features and intended uses are identical. Any differences between the ***Arthrex Bio-Suture*** and the predicate devices are considered minor and do not raise questions concerning safety and effectiveness. Based on the biocompatibility and tensile testing performed, Arthrex, Inc. has determined that the ***Arthrex Bio-Suture*** is substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

APR - 6 2012

Arthrex, Inc.
% Courtney Smith, RAC
Regulatory Affairs Manager
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K112899
Trade/Device Name: Arthrex Bio-Suture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: II
Product Code: GAT
Dated: March 22, 2012
Received: March 28, 2012

Dear Courtney 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

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

Enclosure

K112899

3 Indications for Use Form

Indications for Use

510(k) Number: _____

Device Name: ***Arthrex Bio-Suture***

Indications For Use:

The ***Arthrex Bio-Suture*** is intended for use in 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.

Prescription Use _X_ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112899

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