JUL 3 1 2013

2.1 510(K) SUMMARY

K132043 Page 1/2

Date Summary Prepared	July 30, 2013
Manufacturer/Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Leon Brown II, Ph.D. Regulatory Affairs Specialist Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 2028 Fax: 239/598.5508 Email: Leon.Brown@Arthrex.com
Trade Name	Arthrex ***SpeedCinch***
Common Name	Fastener, fixation, nondegradable soft tissue
Product Code -Classification Name	MBI - Fastener, Fixation, Nondegradable, Soft Tissue GAT - Suture, Nonabsorbable, Synthetic, Polyethylene
CFR	21 CFR 878.5000: Nonabsorbable poly(ethylene terephthalate) surgical suture 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Predicate Device	*K073149:* Arthrex ***Meniscal Cinch***
Purpose of Submission	This special 510(k) premarket notification is submitted to obtain clearance for the Arthrex ***SpeedCinch***.
Device Description	The Arthrex ***SpeedCinch*** is an implantable suture retention device which consists of implants and an implant delivery mechanism. The implants are composed of PEEK Optima® (polyetheretherketone) anchors and FiberWire (Polyethylene/Polyester) suture offered in #2-0 size. The implant delivery mechanism is a handheld manual surgical instrument with trigger for implant delivery.

Intended Use	The Arthrex ***SpeedCinch*** is an implantable suture retention device which facilitates percutaneous or endoscopic soft tissue repairs, including the repair of meniscal tears.
Substantial Equivalence Summary	Based on the intended use, technological characteristics and comparison to the predicate device, Arthrex, Inc. has determined that the proposed Arthrex ***SpeedCinch*** is substantially equivalent to the currently marketed predicate device, Arthrex ***Meniscal Cinch*** (K073149). The Arthrex ***SpeedCinch*** is an implantable suture retention device which consists of implants and an implant delivery mechanism. The proposed device implant has a smaller diameter than the predicate device for lower profile anchoring. Mechanical testing data demonstrates that the tensile strength (pull out strength) and cyclic displacement of the proposed Arthrex ***SpeedCinch*** device are substantially equivalent to or better than the tensile strength and cyclic displacement of the predicate device. The implant materials and general function of the implant are the same as the predicate device. The implant delivery mechanism of the proposed device has been modified for ascetics and to move the implant delivery trigger from being a thumb trigger to being a forefinger trigger for ergonomic ease of use. A nose cover depth stop was added. A downward slant nose option was added to accommodate physician preference. Any differences between the Arthrex ***SpeedCinch*** and the predicate are considered minor and do not raise questions concerning safety and effectiveness.

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 31, 2013

Arthrex, Incorporated
% Mr. Leon Brown II, Ph.D.
Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K132043
Trade/Device Name: Arthrex *SpeedCinch*
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly (ethylene terephthalate) surgical suture
Regulatory Class: Class II
Product Code: GAT, MBI
Dated: July 9, 2013
Received: July 17, 2013

Dear Mr. Brown:

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,

Mark N. Melkerson -S

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

Enclosure

2.5 INDICATIONS FOR USE

Indications for Use

510(k) Number (if known):

K132043

Device Name:

Arthrex *SpeedCinch*

Indications For Use:

The Arthrex ***SpeedCinch*** is an implantable suture retention device which facilitates percutaneous or endoscopic soft tissue repairs, including the repair of meniscal tears.

Prescription Use _✓_ 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 -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K132043