Smith & Nephew TFCC FAST-FIX Kit
510(k) Summary of Safety and Effectiveness

Date prepared: November 13, 2013

Submitter Information	Contact Information
Smith & Nephew, Inc., Endoscopy Division 150 Minuteman Road Andover, MA 01810	Jason Sells Group Manager, Regulatory Affairs Phone: (901) 399-5520 Fax: (901) 566-7084

DEC 05 2013

Device Name (Unmodified)	
Trade or proprietary name	TFCC FAST-FIX Kit
Common or usual name	Suture retention device
Classification name	21 CFR §878.5000 Suture, Non-absorbable, Synthetic, Polyethylene
Product code	GAT

Legally Marketed Predicate Device

The Smith & Nephew TFCC FAST-FIX Kit is substantially equivalent in intended use and Fundamental Scientific Technology to the following legally marketed devices in commercial distribution:

K092508 **FAST-FIX 360 Meniscal Repair System**
(Cleared January 28, 2012)

K072322 **ULTRA FAST-FIX and ULTRA FAST-FIX AB Meniscal Repair Systems**
(Cleared September 18, 2007)

Device Description

The TFCC FAST-FIX Kit is an all-inside Triangular Fibrocartilage Complex (TFCC) repair system. The kit consists of the delivery device pre-assembled with a disposable split cannula and also packaged with a knot pusher/ suture cutter. The delivery device includes two non-absorbable polymer implants (Polyetheretherketone (PEEK)), pre-tied with #2-0 non-absorbable suture (Ultra High Molecular Weight Polyethylene (UHMWPE)) and preloaded into a needle delivery system.

Indications For Use

The Smith & Nephew TFCC FAST-FIX Kit is intended for use as a suture retention device to facilitate Triangular Fibrocartilage Complex (TFCC) repair procedures.

Technological Characteristics

The Smith & Nephew TFCC FAST-FIX Kit is substantially equivalent in design and fundamental scientific technology to the defined predicate devices and raise no new issues of safety and efficacy. Further detail is provided in the table below.

	FAST-FIX 360 (Predicate Device)	TFCC FAST-FIX Kit (Subject Device)
510(k)	**K092508**	**K132079**
Description	The FAST-FIX 360 Meniscal Repair System is an all-inside meniscal repair device. Each device includes two non-absorbable polymer implants, pre-tied with #2-0 non-absorbable suture and preloaded into a needle delivery system. The adjustable depth penetration limiter is preset to approximately 18 mm from the tip of the needle. It can be adjusted down in 2 mm increments to approximately 10 mm.	The TFCC FAST-FIX Kit is an all-inside TFCC repair system. The kit consists of the delivery device pre-assembled with a disposable split cannula and also packaged with a Knot pusher/ Suture cutter. The delivery device includes two non-absorbable polymer implants, pre-tied with #2-0 non-absorbable suture and preloaded into a needle delivery system
Implant Material	Polyetheretherketone (PEEK)	Same
T1 Implant dimensions:	0.200 x 0.040 inches	Same
T2 Implant dimensions	0.190 x 0.059 inches	Same
Suture	Ultra high molecular weight polyethylene (UHMWPE)	Same
Suture Knot	Patented one-way self-locking sliding knot tied with 2 suture retention bar implants	Same
Suture Size	#2-0	Same
Delivery Needle	Stainless Steel	Same
Needle shaft OD	Outer Diameter 0.058"	Same
Depth Limiter Tube	Pebax (White)	Same
Depth Limiter Tube length	5.399"	3.94"
Suture Retaining Tube	Nylon 101	Same
Sterilization	100% EtO (SAL 10^{-6})	Same
How provided	Sterile, Single Use Only	Same
Packaging Configuration	Carton, Paper Carrier, Two pouches (inner and outer)	• Carton and Paper Carrier identical. • One pouch only (same as inner pouch of predicate) • Device has Split Cannula pre-assembled. • There is additional pouch with Knot Pusher/Suture Cutter.
Shelf Life	3 Years	Same

Performance Data

Mechanical testing was conducted and the results were compared to the testing conducted on predicate devices. The Ultimate tensile strength tests and tests to determine load at 2mm elongation confirmed that the TFCC FAST-FIX construct is at least equivalent to the predicate devices and that there are no new issues related to safety and effectiveness of the subject devices. Clinical data was not needed to support the safety and effectiveness of the subject device.

Conclusion

The subject TFCC FAST-FIX Kit may be considered substantially equivalent to the identified predicate devices based on similarities in design and indications for use. The results of mechanical testing performed on the subject device did not raise any new issues of safety or effectiveness, and the TFCC FAST-FIX Kit performed at least equivalent to the identified predicates.

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

Smith & Nephew, Incorporated
Mr. Jason Sells
Senior Regulatory Affairs Specialist
150 Minuteman Road
Andover, Massachusetts 01810

December 5, 2013

Re: K132079
Trade/Device Name: TFCC FAST-FIX Kit
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: Class II
Product Code: GAT
Dated: November 14, 2013
Received: November 15, 2013

Dear Mr. Sells:

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,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
For Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K132079

Device Name: TFCC FAST-FIX Kit

Indications for Use:

The Smith & Nephew TFCC FAST-FIX Kit is intended for use as a suture retention device to facilitate Triangular Fibrocartilage Complex (TFCC) repair procedures.

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

(Per 21 CFR 801 Subpart D) (Part 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: K132079