February 1, 2021

Smith & Nephew, Inc.
Crystal Morales
Regulatory Affairs Specialist II
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Re: K203393
Trade/Device Name: Fast-fix Flex
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: December 4, 2020
Received: December 7, 2020

Dear Ms. Morales:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203393

Device Name
FAST-FIX FLEX

Indications for Use *(Describe)*
The FAST-FIX FLEX Meniscal Repair System is indicated for use in meniscal repairs, allograft transplant procedures, and anchoring the allograft to the meniscal rim during allograft transplant procedures.

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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510(k) Summary

Prepared: 26 January 2021

Submitter Information	Contact Information
Smith & Nephew, Inc. Endoscopy Division 150 Minuteman Road Andover, MA 01810	Crystal Morales Regulatory Affairs Specialist II Phone: (267)-266-5383 Fax: (978) 749-1443

Device Name & Classification	
Proprietary Name	FAST-FIX° FLEX
Common Name	Suture Retention Device
Classification Name	Suture, nonabsorbable, synthetic, polyethylene
Classification Regulation	21 CFR §878.5000
Class	II
Product Code(s)	GAT
Panel	General and Plastic Surgery

Legally Marketed Predicate Devices

The Smith & Nephew FAST-FIX° FLEX Meniscal Repair System is substantially equivalent in intended use and fundamental scientific technology to the following legally marketed devices in commercial distribution:

Description	Submission Number	Clearance Date
Smith & Nephew FAST-FIX 360 Meniscal Repair System	K121861	18 OCT 2012

Device Description

FAST-FIX° FLEX is comprised of an implant-suture construct incorporating #2-0 non-absorbable Ultra-high Molecular Weight Polyethylene (UHMWPE) suture having a pre-tied one-way sliding knot between two non-absorbable polyetheretheketone (PEEK) polymer implants. The suture-implant construct is preloaded into a needle delivery inserter. The needle delivery inserter is offered in two device configurations of curved and reverse curved, whose needle can be modified by the end user with a supplied Bend Tool. The Bend Tool is a sterile, single use optional non-measuring accessory intended to control the bend radius and limit the bend angle to ensure reliable deployment of implants after modification. A sterile, single use slotted cannula is also supplied with the system.

Intended Use

The FAST-FIX® FLEX is indicated for use in meniscal repairs, allograft transplant procedures, and anchoring the allograft to the meniscal rim during allograft transplant procedures.

The Indications for Use statement for FAST-FIX FLEX is different from that of the predicate device FAST-FIX 360 Meniscal Repair System (K121861). The differences are for clarification of content and does not impact the intended use of the device nor the safety and effectiveness of the device in relation to the predicate.

As with the predicate device, the Smith & Nephew FAST-FIX FLEX Meniscal Repair System is intended for use as a suture retention device to facilitate percutaneous or endoscopic soft tissue procedures.

Technological Characteristics

The Smith & Nephew FAST-FIX® FLEX and predicate device FAST-FIX 360 Meniscal Repair System (K121861) uses an all-inside technique through an arthroscopic portal to allow surgeons to reduce tears. The devices use identical suture-implant construct materials that is preloaded into a needle delivery inserter.

Differences in technological characteristics of FAST-FIX FLEX in comparison to the predicate device include, distal needle curvature adjustment with a supplied bend tool, smaller suture bar implants for less disruption to soft tissue and design feature modification to improve implant retention.

The Smith & Nephew FAST-FIX FLEX is substantially equivalent in intended use and fundamental scientific technology as the legally marketed predicate device and raise no new questions of safety and efficacy.

Summary Performance Data

The nonclinical performance data provided in the premarket notification in support of substantial equivalence included biocompatibility testing, sterilization evaluation, implant repair testing, implant bridge strength, tensile strength through cyclic loading and implant failure testing.

The biocompatibility of the FAST-FIX® FLEX was evaluated against the requirements per ISO 10993-1:2018. Evaluation included assessment of existing data, chemical characterization, and cytotoxicity, which provided framework for requiring additional endpoint testing. All acceptance criteria were met and FAST-FIX FLEX was deemed biologically safe.

Sterilization validation methods of FAST-FIX FLEX was compared to the predicate device FAST-FIX 360 Meniscal Repair System (K121861) to demonstrate suitability of the subject device for terminal sterilization under the same conditions.

The performance data demonstrates that FAST-FIX® FLEX met performance specifications for implant repair and implant bridge strength and met performance specifications for tensile strength through cyclic loading and implant failure testing based on established acceptance

criteria and in comparison to the predicate device FAST-FIX 360 Meniscal Repair System (K121861).

Therefore, the FAST-FIX FLEX is considered substantially equivalent to the currently marketed predicate.

Substantial Equivalence Information

The substantial equivalence of the FAST-FIX◇ FLEX is based on similarities in indications for use, general design features, operational principles, material biocompatibility and composition, and performance to the predicate, FAST-FIX 360 Meniscal Repair System (K121861). Based on the similarities to the predicate, the FAST-FIX FLEX is equivalent to its predicates.