July 9, 2026

Smith & Nephew, Inc.
Xianjun Chen
Principal Regulatory Specialist
150 Minuteman Rd.
Andover, Massachusetts 01810

Re: K261968
Trade/Device Name: Q-FIX KNOTLESS All-Suture Anchor, 2.8mm, with one black knotless and one blue MINITAPE suture (72205981); Q-FIX KNOTLESS All-Suture Anchor, 2.8mm, with one blue knotless and one black MINITAPE suture (72205982)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: June 11, 2026
Received: June 11, 2026

Dear Xianjun Chen:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261968

Please provide the device trade name(s).

Q-FIX◊ KNOTLESS All-Suture Anchor, 2.8mm, with one black knotless and one blue MINITAPE◊ suture (72205981);
Q-FIX◊ KNOTLESS All-Suture Anchor, 2.8mm, with one blue knotless and one black MINITAPE◊ suture (72205982)

Please provide your Indications for Use below.

The Q-FIX◊ Knotless All-Suture Anchor is intended for use for soft tissue to bone fixation for the following indications:
Shoulder: Acromio-clavicular repair; Capsular shift/capsulolabral reconstruction; Deltoid repair; Rotator cuff tear repair; Biceps tenodesis.
Foot & Ankle: Medial/Lateral repair and reconstruction; Midfoot and forefoot repair; Hallux valgus reconstruction; Metatarsal ligament/ tendon repair or reconstruction; Achilles tendon repair.
Elbow: Ulnar or radial collateral ligament reconstruction; Lateral epicondylitis repair; Biceps tendon reattachment.
Knee: Extra-capsular repair: medial collateral ligament (MCL), lateral collateral ligament (LCL) and posterior oblique ligament; Iliotibial band tenodesis (IBT); Patellar tendon repair; Vastus medialis obliquus advancement (VMO); Joint capsule closure.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

Smith & Nephew, Inc.
150 Minuteman Road
Andover, MA 01810
Massachusetts, USA

T:+ 1 978 749 1000
T:+ 1 800 343 8386 (USA toll free)
www.smith-nephew.com

Smith+Nephew

510(k) Summary

Revised: July 7, 2026

Submitter Information	Contact Information
Smith & Nephew, Inc. Endoscopy Division 150 Minuteman Road Andover, MA 01810	Ms. Xianjun Chen Principal Regulatory Affairs Specialist xianjun.chen@smith-nephew.com

Device Name & Classification	
Proprietary Name	Q-FIX◊ KNOTLESS All-Suture Anchor, 2.8mm, with one black knotless and one blue MINITAPE◊ suture Q-FIX◊ KNOTLESS All-Suture Anchor, 2.8mm, with one blue knotless and one black MINITAPE◊ suture
Common Name	Soft Tissue Fixation Device
Classification Name	Fastener, fixation, biodegradable, soft tissue; fastener, fixation, nondegradable, soft tissue
Classification Regulation	21 CFR 888.3040
Class	II
Product Code(s)	MBI
Panel	Orthopedic

Legally Marketed Predicate Device

The new 2.8mm Smith & Nephew Q-FIX◊ Knotless All-Suture Anchor is substantially equivalent in intended use and fundamental scientific technology to the following legally marketed devices in commercial distribution:

Description	Submission Number	Clearance Date
Q-FIX◊ Suture Anchor	K172165 (secondary predicate)	17 AUG 2017
Q-FIX◊ Knotless All-Suture Anchors	K241435 (primary predicate)	20 JUN 2024

Device Description

The new 2.8mm Smith & Nephew Q-FIX◊ Knotless All-Suture Anchor is a fixation device intended to provide fixation of soft tissue to bone. Each device consists of one (1) PET anchor, one (1) UHMWPE repair suture, one (1) free-sliding MINITAPE◊, one (1) UHMWPE transfer suture. The difference between the two implant configurations is in the suture color offering; one configuration (72205981) has black repair suture and blue MINITAPE, the other one (72205982) has blue repair suture and black MINITAPE. The two new devices will maintain compatibility with the existing 2.8mm Q-FIX Suture Anchor instrumentation (drills, guides, and obturators). The subject device is supplied sterile, for single use only.

Intended Use

The Q-FIX Knotless All-Suture Anchors are intended for use during surgical procedures for fixation of soft tissue to bone.

Indications for Use

The Q-FIX◊ Knotless All-Suture Anchor is intended for use for soft tissue to bone fixation for the following indications:

Shoulder:

- Acromio-clavicular repair
- Capsular shift/capsulolabral reconstruction
- Deltoid repair
- Rotator cuff tear repair
- Biceps tenodesis

Foot & Ankle:

- Medial/Lateral repair and reconstruction
- Midfoot and forefoot repair
- Hallux valgus reconstruction
- Metatarsal ligament/tendon repair or reconstruction
- Achilles tendon repair

Elbow:

- Ulnar or radial collateral ligament reconstruction
- Lateral epicondylitis repair
- Biceps tendon reattachment

Knee:

- Extra-capsular repair: medial collateral ligament (MCL), lateral collateral ligament (LCL) and posterior oblique ligament
- Iliotibial band tenodesis (IBT)
- Patellar tendon repair
- Vastus medialis obliquus advancement (VMO)
- Joint capsule closure

Technological Characteristics

The 2.8mm Q-FIX◊ Knotless All-Suture Anchor is an expansion to the legally marketed 1.8mm Q-FIX◊ Knotless All-Suture Anchor (K241435) and Q-FIX◊ Suture Anchor (K172165) All-Suture Anchor product family. The modifications to the legally marketed predicate devices include introducing a 2.8mm knotless suture anchor, adding repair suture with black colorant, adding one (1) free-sliding MINITAPE◊ repair suture, and new packaging configuration. The new 2.8 Q-FIX Knotless devices contain the same implant and inserter components to legally marketed Q-FIX 2.8 All-Suture Anchor (K172165). The implant is pre-loaded with a knotless suture construct consisting of a single repair suture and two limbs of transfer suture which is the same as the current marketed Q-FIX Knotless with MINITAPE (K241435). An additional sliding MINITAPE suture will be included in the implant to enable a variety of repair constructs.

The new devices utilize the same knotless feature as the legally marketed predicate device 1.8mm Q-FIX Knotless Suture Anchors (K241435). They have the same implant deployment mechanism and insertion/fixation/cyclic performance to either the marketed Q-FIX Knotless Suture Anchors or the Q-FIX All-Suture Anchors (K172165). The implant material (polyester) of the subject device is identical to the implant material of the legally marketed predicate devices. The intended use and indications for use, and sterilization method of the subject device remain the same as the currently marketed Q-FIX Knotless All-Suture Anchor. Additionally, many of the subject device components

are identical compared to predicates. The differences between the subject device and predicate device are minor and raise no new questions of safety of effectiveness.

Performance Data

Non-clinical bench testing was completed on the subject device, and the device met all required specifications for each test. Testing included insertion testing, fixation testing, cyclic loading testing, load to pass testing, packaging design verification. A summary of test acceptance criteria and results have been provided. Results for all tests passed.

The biocompatibility of Q-FIX◊ Knotless All-Suture Anchor was evaluated against the requirements per ISO 10993-1 and was deemed biologically safe.

Conclusion

The substantial equivalence of the 2.8mm Q-FIX◊ Knotless All-Suture Anchor is based on similarities in indications for use, design features, operational principles, material biocompatibility and composition, and performance to the predicate devices listed above. Modifications in design are minor and do not raise additional questions of safety or effectiveness compared to the predicate device. Based on the similarities, 2.8mm Q-FIX◊ Knotless All-Suture Anchor is substantially equivalent to its predicates.