June 20, 2024

Smith & Nephew, Inc.
Rebecca Peterkins
Regulatory Affairs Specialist II
150 Minuteman Road
Andover, Massachusetts 01810

Re: K241435

Trade/Device Name: Q-FIX◊ Knotless All-Suture Anchor, 1.8 mm, with one ULTRABRAID◊ suture, blue; Q-FIX◊ Knotless All-Suture Anchor, 1.8 mm, with one ULTRABRAID◊ suture, co-braid-blue; Q-FIX◊ Knotless All-Suture Anchor, 1.8 mm, with one MINITAPE◊ suture, blue; Q-FIX◊ Knotless All-Suture Anchor, 1.8 mm, with one MINITAPE◊ suture, co-braid-blue

Regulation Number: 21 CFR 888.3040

Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener

Regulatory Class: Class II

Product Code: MBI

Dated: May 21, 2024

Received: May 21, 2024

Dear Ms. Peterkins:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,

Robert M. Stefani -S

Digitally signed by Robert M. Stefani -S
Date: 2024.06.20 13:47:43 -04'00'

For: Jesse Muir, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K241435

Device Name

Q-FIX◊ Knotless All-Suture Anchor, 1.8 mm, with one ULTRABRAID◊ suture, blue;
Q-FIX◊ Knotless All-Suture Anchor, 1.8 mm, with one ULTRABRAID◊ suture, co-braid-blue;
Q-FIX◊ Knotless All-Suture Anchor, 1.8 mm, with one MINITAPE◊ suture, blue;
Q-FIX◊ Knotless All-Suture Anchor, 1.8 mm, with one MINITAPE◊ suture, co-braid-blue

Indications for Use *(Describe)*

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

Shoulder:
- Bankart lesion repair
- SLAP lesion repair
- 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

Hip:
- Acetabular labral repair

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: 20 June 2024

| Submitter Information | Contact Information |
|---|---|
| Smith & Nephew, Inc.<br>Endoscopy Division<br>150 Minuteman Road<br>Andover, MA 01810 | Ms. Rebecca Peterkins<br>Regulatory Affairs Specialist II<br>rebecca.peterkins@smith-nephew.com<br>(978) 749-1057 |

| Device Name & Classification | |
|---|---|
| Proprietary Name | Q-FIX◊ Knotless All-Suture Anchor, 1.8mm, with one ULTRABRAID◊ suture, blue<br>Q-FIX◊ Knotless All-Suture Anchor, 1.8mm, with one ULTRABRAID◊ suture, co-braid-blue<br>Q-FIX◊ Knotless All-Suture Anchor, 1.8mm, with one MINITAPE◊ suture, blue<br>Q-FIX◊ Knotless All-Suture Anchor, 1.8mm, with one MINITAPE◊ suture, co-braid-blue |
| Common Name | Soft Tissue Fixation Device |
| Classification Name | Fastener, Fixation, Nondegradable, Soft Tissue |
| Classification Regulation | 21 CFR 888.3040 |
| Class | II |
| Product Code(s) | MBI |
| Panel | Orthopedic |

## Legally Marketed Predicate Device

The 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 | 17AUG2017 |

## Legally Marketed Reference Devices

| Description | Submission Number | Clearance Date |
|---|---|---|
| **MINITAPE◊ Suture** | K132357 | 30OCT2013 |
| **ULTRABRAID◊ Suture** | K101377 | 08APR2011 |

## Device Description

The Smith & Nephew Q-FIX◊ Knotless All-Suture Anchor is a fixation device intended to provide fixation of soft tissue to bone. The device consists of an all-suture anchor preloaded with one (1) transfer suture and either one (1) ULTRABRAID◊ or MINITAPE◊ suture assembled inside an insertion device. The device is supplied sterile, for single use only.

The 1.8mm implant (all-suture anchor) is made of braided polyester with either one strand of ULTRABRAID◊ or MINITAPE◊ suture and one transfer suture pre-loaded. The ULTRABRAID◊, MINITAPE◊, and transfer sutures are non-absorbable sutures of ultra-high molecular weight polyethylene (UHMWPE). The Q-FIX◊ Knotless All-Suture Anchor has a knotless suture locking mechanism that provides adjustable one-way tensioning.

## Intended Use

The Q-FIX◊ Knotless All-Suture Anchor is intended for use during surgical procedures for the 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:**

- Bankart lesion repair
- SLAP lesion repair
- 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

**Hip:**

- Acetabular labral repair

## Technological Characteristics

| | Q-FIX◊ Knotless All-Suture Anchor *(Subject Device)* | Predicate Q-FIX◊ Suture Anchor *(K172165)* |
|---|---|---|
| **Intended Use** | Soft tissue to bone fixation | Same |
| **Indications for Use** | **Shoulder:**<br>• Bankart lesion repair<br>• SLAP lesion repair<br>• Acromio-clavicular repair<br>• Capsular shift/capsulolabral reconstruction<br>• Deltoid repair<br>• Rotator cuff tear repair<br>• Biceps tenodesis<br>**Foot & Ankle:**<br>• Medial/Lateral repair and reconstruction<br>• Midfoot and forefoot repair<br>• Hallux valgus reconstruction<br>• Metatarsal ligament/tendon repair or reconstruction<br>• Achilles tendon repair<br>**Elbow:**<br>• Ulnar or radial collateral ligament reconstruction<br>• Lateral epicondylitis repair<br>• Biceps tendon reattachment<br>**Knee:**<br>• Extra-capsular repair: medial collateral ligament (MCL), lateral collateral ligament (LCL) and posterior oblique ligament<br>• Iliotibial band tenodesis (IBT)<br>• Patellar tendon repair<br>• Vastus medialis obliquus advancement (VMO)<br>• Joint capsule closure<br>**Hip:**<br>• Acetabular labral repair | Subset of predicate device |
| **Delivery Method** | Arthroscopic and mini open | Same |
| **How Supplied** | Packaged in thermoform tray with Tyvek lid, Sterile (EtO), Single Use | Same |
| **Shelf Life** | 3 years | Same |
| **MR Compatibility** | MR Safe | Same |
| **Anchor Material** | Polyester (PET) | Same |
| **Suture Material** | UHMWPE (ultra-high molecular weight polyethylene) | Same |
| **Inserter Shaft Materials** | Stainless Steel | Same |

| | | |
|---|---|---|
| **Inserter Handle Materials** | Polycarbonate, ABS, Nylon | Same |
| **Method of Anchor Insertion** | Inserted into a predrilled hole | Same |
| **Inserter Shaft Working Length** | 8.60 in | Same as Q-FIX◊ 1.8mm Suture Anchor |
| **Bone Locking Mechanism** | Expandable Compression Fit | Same |
| **Suture Locking Mechanism** | Knotless suture mechanism | Manually tied suture knot |
| **Size Offered (Diameter)** | 1.8mm | Same as Q-FIX◊ 1.8mm Suture Anchor |
| **Suture Size (USP)** | #2 or MINITAPE (#2) | Same |
| **Number of Suture Legs** | 3 | Within range of predicate device |
| **Bone Hole OD** | 2.1 mm | Same as Q-FIX◊ 1.8mm Suture Anchor |
| **Bone Hole Depth** | 22.3 mm | Same as Q-FIX◊ 1.8mm Suture Anchor |
| **Accessories** | Nonsterile, reusable and sterile, disposable drills, drill guides, and obturators | Subset of predicate device |

Q-FIX◊ Knotless All-Suture Anchor is an iterative design of the legally marketed Q-FIX◊ Suture Anchor (K172165). The modifications to the legally marketed predicate device Q-FIX◊ Suture Anchor (K172165) include adding one (1) transfer and either one (1) ULTRABRAID◊ or MINITAPE◊ repair suture to facilitate a knotless repair. Q-FIX◊ Knotless All-Suture Anchor is similar in its intended use, indications for use, sterilization method, materials, packaging configuration, and design. The ULTRABRAID◊ and MINITAPE◊ sutures in the subject device are similar to the reference devices cleared under K132357 & K101377. Additionally, many of the subject device components are identical compared to the predicate. 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, and knot tensile strength testing. 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.

Based on similarities to the subject device repair sutures, reference devices, ULTRABRAID◊ and MINITAPE◊, were included to support product performance and biocompatibility.

## Conclusion

The substantial equivalence of the 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/reference 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, Q-FIX◊ Knotless All-Suture Anchor is substantially equivalent to its predicate.