August 9, 2023

Smith & Nephew Inc.
Pragnya Bakka
Senior Regulatory Affairs Specialist
150 Minuteman Road
Andover, Massachusetts 01810

Re: K231376
Trade/Device Name: Q-FIX◊ With Needles
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: May 8, 2023
Received: May 12, 2023

Dear Pragnya Bakka:

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,

Jesse Muir -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231376

Device Name
Q-FIX◊ with Needles

Indications for Use *(Describe)*
Q-FIX with Needles use is only intended for the reattachment of soft tissue to bone for the following indications:

Foot and Ankle
• Medial or lateral instability repairs/reconstructions
• Achilles tendon repairs/reconstructions

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.

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K231376

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1 GENERAL INFORMATION

Submitter Name	Smith & Nephew, Inc.
Address	150 Minuteman Road, Andover, MA 01810, USA
Contact Person	Pragnya Bakka Senior Regulatory Affairs Specialist
Date Prepared	11 May 2023

2 DEVICE NAME(S)

Proprietary Name	Q-FIX◊ with Needles
Common Name	Q-FIX◊ with Needles, #0 SUTURE Q-FIX◊ with Needle, MINITAPE Q-FIX◊ All-Suture Anchor with Needles.
Classification Name	Smooth or threaded metallic bone fixation fastener
Device Class	Class II
Product Code	MBI
CFR Section	21 CFR 888.3040

3 PREDICATE DEVICE(S)

Primary Predicate	Q-FIX ® Suture Anchor (K172165)
Secondary Predicate Device	RAPTORMITE 3.0 PK Suture Anchor (K071586)
Reference Device	Bioraptor Knotless Suture Anchor (K093428)

4 SUBJECT DEVICE (s) DESCRIPTION

Q-FIX◊ with Needles is an all-suture anchor that consists of a fixation device intended to provide the reattachment of tissue to bone. The 1.8 mm implant is manufactured from braided polyester with ultra high molecular weightpolyethylene (UHMWPE) sutures with needles and is pre-loaded into a disposable tool designed to facilitate direct insertion into a pre-drilled bone hole. The device includes a handle and a deployment knob used to deploy one soft anchor implant into the joint spaceand a suture with needles compartment with a release handle.

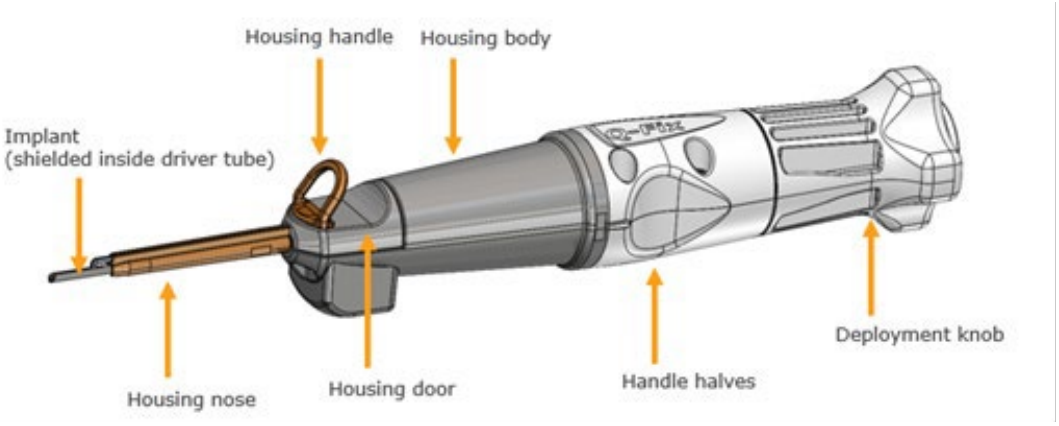


Figure 1 Components of Q-FIX with Needles

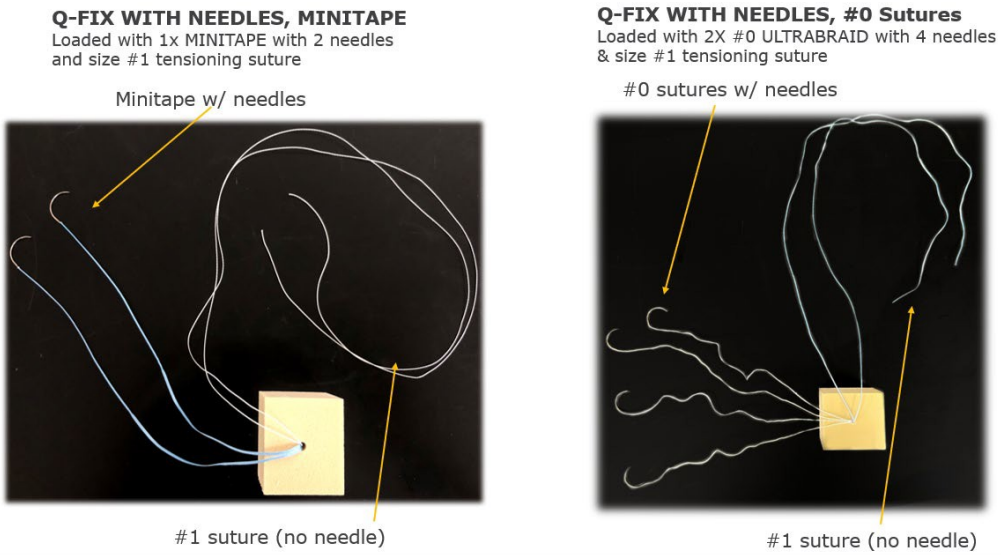


Figure 2 Q-FIX with Needles (MINITAPE), Q-FIX with Needles (#0 SUTURE)

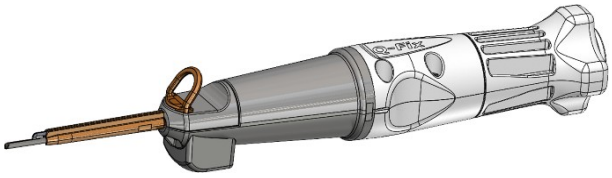
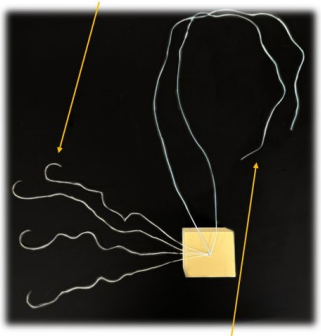
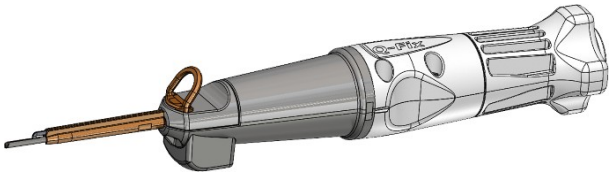
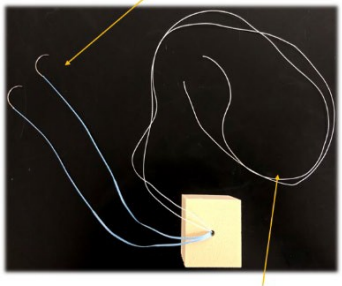
Figure 3 Q-Fix Anchor(1.8mm)

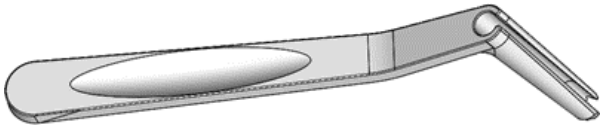
Q-FIX$^{\lozenge}$ with Needles includes two versions,

- Q-FIX with Needles, #0 SUTURE includes an all-sutureanchor loaded with a #1 hot stretched tension suture and 2 #0 repair sutures
- Q-FIX with Needles, MINITAPE includes an all-suture anchor loaded with a #1 hot stretched tension suture and 1 MINITAPE repairsuture

In addition, the Drill for Q-FIX with Needles, 2.2mm and Extremities Guide, Universal, are used to prepare the bone to insert the anchor.

Table 1 Q-FIX$^{\Diamond}$ with Needles Variants, accessories- Pictorial representation

Description	**Pictorial Representation**
Q-FIX with Needles, #0 SUTURE	 
Q-FIX with Needles, MINITAPE	 
Drill for Q-FIX with Needles	

Extremities Guide, Universal	

5 INTENDED USE/INDICATIONS FOR USE

5.1 Intended use:

Q-FIX◊ with Needles is intended for use for the reattachment of soft tissue to bone.

5.2 Indications for use:

Q-FIX with Needles use is only intended for the reattachment of soft tissue to bone for the following indications:

Foot and Ankle

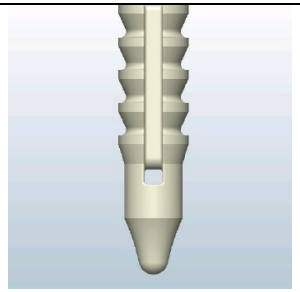
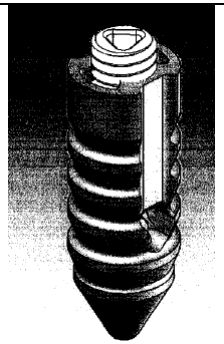
- Medial or lateral instability repairs/reconstructions
- Achilles tendon repairs/reconstructions

6 COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE(S)

See Table 2 below for a summary of the comparison of the technological features between subject and predicate devices.

Table 2: Comparison of Technological Differences between the Subject device, Predicate devices, and reference device.

	Q-FIX◊ with Needles (Subject Device)	**Q-Fix Suture Anchor (1.8mm Q-FIX Mini, 1.8 Q-FIX 2.8 Q-FIX (Primary Predicate)(K172165)**	**Raptormite 3.0 PK Suture Anchor (Secondary Predicate Device) (K071586)**	**Smith & Nephew Knotless Instability Anchor or Bioraptor Knotless Suture Anchor (Reference Device) (K093428)**
Intended Use	Reattachment of soft tissue to bone	Same	Same	Same
Indications for Use	Q-FIX with Needles use is only intended for the reattachment of soft tissue to bone for the following indications: **Foot and Ankle** • Medial or lateral instability repairs/ reconstructions • Achilles tendon repairs/ reconstructions	The Q-Fix Suture Anchor is intended tobe used for soft tissue to bone fixation for: **Shoulder:** Bankart lesion repair, SLAPLesion repair; acromio-clavicular repair, capsular shift/capsulolabral reconstruction, deltoid repair, rotator cuff tear repair, biceps tenodesis **Foot & Ankle:** Medial/Lateral repairand 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 tendonreattachment **Knee:** Extra-capsular repair, Medial collateral ligament (MCL), lateral collateral ligament (LCL), posterior oblique ligament, iliotibial band tenodesis (IBT), patellar tendon repair,vastus medialis obliquus advancement(VMO), Joint capsule closure	These suture anchors are intended for the fixation of soft tissue to bone in the Hip, Shoulder, Foot, Ankle, Elbow, Wrist, Hand and Knee as follows: **Hip** Hip capsular repair -Acetabular labrum reattachment **Shoulder** Capsular stabilization -Bankart repair -Anterior shoulder instability -SLAP lesion repairs -Capsular shift or capsulolabral reconstructions Acromio-clavicular separation repair Deltoid repair Rotator cuff tear repair Biceps tenodesis **Foot and Ankle** Hallux valgus repairs Medial or lateral instability repairs/reconstructions	The Smith & Nephew Knotless Instability Anchor is intended for reattachment of soft tissue to bine for following indications: **Hip** • Acetabular labrum reattachment **Shoulder** Capsular stabilization • Bankart repair • Anterior shoulder instability • SLAP lesion repairs • Capsular shift or capsulolabral reconstructions Acromioclavicular separation repairs Deltoid repairs Rotator cuff tear repairs Biceps tenodesis **Foot and Ankle** Hallux valgus repairs Medial or lateral instability repairs/reconstructions Achilles tendon repairs/reconstructions Metatarsal ligament/tendon repair or reconstruction Bunionectomy

		Hand and Wrist: Collateral ligament repair; Scapholunate ligament reconstruction; Tendon transfers in plalanx; Volar plate reconstruction **Hip** Acetabular labral repair	Achilles tendon repairs/reconstructions Midfoot reconstructions Metatarsal ligament/tendon repair or reconstruction Bunionectomy **Elbow, Wrist, and Hand** Biceps tendon reattachment • Ulnar or radial collateral ligament reconstructions Lateral epicondylitis repair **Knee** • Extra-capsular repair: -Medial collateral ligament -Lateral collateral ligament -Posterior oblique ligament Patellar realignment and tendon repairs -Vastus medialis obliquus advancement Iliotibial band tenodesis	**Elbow, Wrist, and Hand** Biceps tendon reattachment Ulnar or radial collateral ligament reconstructions Lateral epicondylitis repair **Knee** Extra-capsular repair: • Medial collateral ligament • Lateral collateral ligament • Posterior oblique ligament Patellar realignment and tendon repairs • Vastus medialis obliquus advancement Iliotibial band tenodesis
Anchor Pictorial representation		2.8mm  1.8mm  1.8 Mini 		
Implant/ Anchor Material	Polyethylene Terephthalate Fiber (PET)	Same	poly-ether-ether-ketone (PEEK)	poly-ether-ether-ketone (PEEK)

Anchor/ Implant size (Diameter)	1.8 mm	1.8 and 2.8 mm	3.0 mm	3.7 mm
Implant Length (before deployment)	10mm	15mm for 1.8mm Q-Fix Anchor 20mm for 2.8mm Q-Fix Anchor 10mm for 1.8mm Q-Fix MINI anchor	0.455" (11.557 mm)	0.480" (12.192 mm)
Bone Hole OD	0.0875" (2.2 mm)	2.1mm (0.083") for 1.8mm Q-Fix Anchor 3.1mm (0.121") for 2.8mm Q-Fix Anchor	2.6 mm	4 mm
Bone hole depth	0.71" (18.034 mm)	22.3mm for 1.8mm Q-Fix Anchor 26.8mm for 2.8mm Q-Fix Anchor 17.1mm for 1.8mm Q-Fix MINI Anchor	14 mm	21.5 mm
Suture Size (USP)	#0 and #1 Or MINITAPE (#2) and #1	#2	#0	#2-0
Number of Sutures	Q-FIX$^{\lozenge}$ with Needles, #0 SUTURE: 3 (#0, #1) Q-FIX$^{\lozenge}$ with Needles, MINITAPE: 2 (#1, #2)	1.8mm Q-Fix Anchor: 1 (#2 Suture) 2.8mm Q-Fix Anchor: 2 (#2 Suture)	2 (#0 Suture)	1 (#2-0)
Suture Material	UHMWPE, nonabsorbable Polypropylene, nonabsorbable	Same	Same	Same

Inserter Shaft Material	Stainless Steel	Same	Same	Same
Inserter Handle Material	Polycarbonate ABS Nylon Stainless Steel	Polycarbonate ABS Nylon Stainless Steel	Polycarbonate Stainless Steel Silicone	Polycarbonate ABS Stainless Steel
Labeling	Rx Only, Sterile, Single-Use	Same	Same	Same
Method of Sterilization	EtO	EtO	EtO	Gamma
Packaging Configuration	2-piece PETG inner tray	2-piece PETG inner tray	LPDE tip protector in a PE bag and single Tyvek pouch inside a CCB outer carton	LPDE tip protector in a PE bag and single Tyvek pouch inside a CCB outer carton
Method of Anchor Insertion	Insert into a predrilled hole	Same	Same	Same
Suture Locking Mechanism	Manually tied suture knot	Manually tied suture	Manually tied suture	Knotless via inner plug mechanism
Bone Locking Mechanism	Expandable Compression Fit	Expandable Compression Fit	Steps/ribs	Steps/ribs
Needles provided in the device	Q-FIX$^{\lozenge}$ with Needles #0, SUTURE: Four (4) needles Q-FIX$^{\lozenge}$ with Needles, MINITAPE: Two (2) needles	No	Yes (4). Housed within the shaft	No
Accessories used	Drill Drill guide	Nonsterile, Reusable Drill, Drill Guide,	2.3 mm Drill Guide, 2.3 mm Obturator, 2.3 mm Drill Bit	Drill, Drill Guide, Obturator

		Obturator and Sterile, Disposable Drill, Drill Guide, Obturator Bone Punch, Knot Pusher 1.8mm & 2.8mm PathFinder® FirstPass® Suture Passer FirstPass® ST Suture Passer Accu-Pass® Direct Suture Passer SpeedStitch® Suture Passer		Suture Shuttle

8 PERFORMANCE TESTING – NON-CLINICAL

For the non-clinical performance testing, both Q-FIX$^{◊}$ with Needles SKUs have been assessed for the following functional tests:

- Insertion and deployment
    - With the use of the Extremities Guide, Universal and the Drill for Q-FIX with Needles
- Suture slide
- Fixation
- Cyclic UTS and displacement
- Needle attachment strength
- Knot tensile strength

For the non-clinical performance testing, the Drill for Q-FIX with Needles has been assessed for the following functional tests:

- Force and torque to drill
- Torque to fail

Q-FIX with Needles devices met performance specifications for insertion strength, fixation, cyclic loading, UTS. Therefore, Q-FIX with Needles is equivalent to its predicate devices.

9 PERFORMANCE TESTING – PRE-CLINICAL

There was no pre-clinical testing required for the subject device.

10 PERFORMANCE TESTING – ANIMAL

There was no animal testing required for the subject device.

11 PERFORMANCE TESTING – CLINICAL

There are no clinical studies performed on the subject device

12 STERILIZATION

Q-FIX with Needles devices are sterilized utilizing 100% Etyhlene Oxide (Eto orEO) gas via an existing validated EO Cycle. The evaluation and adoption are based onthe principles outlined in AAMI TIR 28:2016. The sterilization method ensures a minimum sterility assurance level of 10^{-6}.

13 SHELF LIFE

Shelf life testing included environmental conditioning (T=0) and accelerated aging studies at T=1 year. Packaging integrity testing included- visual inspection of seal, gross leak (bubble emission), peel strength testing, and manual peel or aseptic presentation.

14 PACKAGING

Q-FIX$^{\lozenge}$ with Needles devices are supplied sterile and are intended for single use only. The devices are not cleaned or re-sterilized for re-use. All packaging has been validated in accordance with ASTM D4332:2014, ISTA 3A, ISTA 4AB, ISO 11607-1:2019 and ISO 11607-2:2019.

15 BIOCOMPATIBILITY

Q-FIX with Needles devices include components that are is classified as an externally communicating medical device with tissue/bone/dentin contact with limitedduration (≤24 h) and Implant, >30 days, as per ISO 10993-1:2018. The subject devicemet the acceptance criteria under the conditions of the chemical characterization and biological testing performed.

16 CONCLUSION

All testing demonstrates that the subject devices perform as intended and have acceptable performance when used in accordance with the labeling. The substantial equivalence of Q-FIX with Needles is based on similarities in indications for use, design features, operational principles, material biocompatibility and composition, and performance to the predicate devices and reference devices listed above.