September 8, 2023

Smith & Nephew
Catherine Phelan
Senior Regulatory Affairs Specialist
150 Minuteman Road
Andover, Massachusetts 01810

Re: K232457
Trade/Device Name: Q-FIX◊ ULTRA All-Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI, GAT, HTW
Dated: August 14, 2023
Received: August 14, 2023

Dear Catherine Phelan:

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)*
K232457

Device Name
Q-FIX◊ ULTRA All-Suture Anchor

Indications for Use *(Describe)*
The Q-FIX◊ ULTRA All-Suture Anchor 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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510(k) Summary

Prepared: 06 September 2023

Submitter Information	Contact Information
Smith & Nephew, Inc. Endoscopy Division 150 Minuteman Road Andover, MA 01810	Ms. Catherine Phelan Senior Regulatory Affairs Specialist catherine.phelan@smith-nephew.com

Device Name & Classification	
Proprietary Name	Q-FIX◇ ULTRA All-Suture Anchor
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 Devices

The Smith & Nephew Q-FIX◇ ULTRA 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
Q-Fix◇ Suture Anchor	K172165

Legally Marketed Reference Device

Description	Submission Number
ULTRATAPE◇ Suture	K132357
Q-FIX◇ with Needles	K231376

Device Description

The Smith & Nephew Q-FIX◇ ULTRA All-Suture Anchor is a fixation device intended to provide reattachment of soft tissue to bone. The device consists of an all-suture anchor with a preloaded ULTRATAPE◇ suture assembled inside an insertion device.

Intended Use

The Q-FIX◇ ULTRA All-Suture Anchor is intended for use for the reattachment of soft tissue to bone.

Indications for Use

The Q-FIX◇ ULTRA All-Suture Anchor is only intended for the reattachment of soft tissue to bone for the following indications:

Foot & Ankle

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

Technological Characteristics

The changes to the legally marketed predicate device (Q-Fix◇ Suture Anchor) include a modified inserter and the addition of preloaded ULTRATAPE◇ Suture.

Q-FIX◇ ULTRA All-Suture Anchor is equivalent in its intended use, indications for use, manufacturing process, sterilization method, materials, packaging configuration, and design. The implantable materials in the subject device are equivalent to the materials of the predicate/reference devices. Additionally, many of the subject device components are identical compared to the predicate/reference devices. 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, static fixation testing, cyclic loading 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◇ ULTRA All-Suture Anchor was evaluated against the requirements per ISO 10993-1 and was deemed biologically safe.

Conclusion

The substantial equivalence of the Q-FIX◇ ULTRA 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. Based on the similarities, Q-FIX◇ ULTRA All-Suture Anchor is substantially equivalent to its predicate.