January 17, 2024

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

Re: K233730
Trade/Device Name: Footprint Mini PK, 3.5mm Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: November 20, 2023
Received: November 21, 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 (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,

Jesse Muir -S Digitally signed by Jesse Muir -S
Date: 2024.01.17 10:41:13 -05'00'

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)*

K233730

Device Name

FOOTPRINT◊ MINI PK, 3.5mm Suture Anchor

Indications for Use *(Describe)*

The FOOTPRINT◊ MINI PK, 3.5mm 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
Knee:
• Extra-capsular repairs
–Medial collateral ligament
–Lateral collateral ligament
–Posterior oblique ligament

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: 08 January 2024

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 (508)-446-4542

Device Name & Classification	
510(k) Number	K233730
Proprietary Name	FOOTPRINT◇ MINI PK, 3.5mm 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 FOOTPRINT◇ MINI PK, 3.5mm Suture Anchor is substantially equivalent in intended use and fundamental scientific technology to the following legally marketed devices in commercial distribution:

Description	Submission Number
Knotless Instability Anchor	K093428
RAPTORMITE◇ 3.0 PK Suture Anchor	K071586

Legally Marketed Reference Device

Description	Submission Number
MICRORAPTOR◇ Knotless Suture Anchor	K181746
FAST-FIX◇ FLEX	K203393

Device Description

The Smith & Nephew FOOTPRINT◇ MINI PK, 3.5mm Suture Anchor is a fixation device intended to provide reattachment of soft tissue to bone. The device consists of a two-piece suture anchor comprised of an anchor body and inner plug, preassembled onto an insertion device. The device is sold with a disposable suture threader.

Intended Use

The FOOTPRINT◇ MINI PK, 3.5mm Suture Anchor is intended for use for the reattachment of soft tissue to bone.

Indications for Use

The FOOTPRINT◇ MINI PK, 3.5mm Suture Anchor is intended for use only for the reattachment of soft tissue to bone for the following indications:

Foot & Ankle

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

Knee

- Extra-capsular repairs
  –Medial collateral ligament
  –Lateral collateral ligament
  –Posterior oblique ligament

Technological Characteristics

The Smith & Nephew FOOTPRINT◇ MINI PK, 3.5mm Suture Anchor is substantially equivalent to the predicate devices, Smith & Nephew Knotless Instability Anchor (K093428) and RAPTORMITE◇ 3.0 PK W/ NEEDLES AND TWO SIZE 0 ULTRABRAID SUTURES, CO-BRAID BLUE & WHITE (also referred to as RAPTORMITE◇ 3.0 PK Suture Anchor) (K071586).

Technological characteristics of the FOOTPRINT◇ MINI PK, 3.5mm Suture Anchor such as intended use, indications for use, manufacturing processes, sterilization method, materials, packaging configuration, and design are equivalent to the predicate devices. Additionally, the implantable materials in the subject device are equivalent to the materials of the predicate devices. Minor differences between the subject device and predicate devices have been evaluated through performance testing to demonstrate substantial equivalence between the subject devices and predicate devices and raise no new questions of safety or 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, and cyclic loading testing. A summary of test acceptance criteria and results have been provided. Results for all tests passed.

Conclusion

The substantial equivalence of the FOOTPRINT◇ MINI PK, 3.5mm Suture Anchor is based on similarities in intended use, indications for use, design features, operational principles, material biocompatibility and composition, sterilization, and performance to the predicate/reference devices listed above. Based on the similarities, FOOTPRINT◇ MINI PK, 3.5mm Suture Anchor is substantially equivalent to its predicates.