August 4, 2023

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

Re: K232005
Trade/Device Name: HEALICOIL◊ PK Suture Anchor with Needles, ULTRATAPE◊ (Blue);
HEALICOIL◊ PK Suture Anchor with Needles, ULTRATAPE◊ (Blue Cobraid)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: July 6, 2023
Received: July 6, 2023

Dear Camille Fleischer:

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)*
K232005

Device Name
HEALICOIL◊ PK Suture Anchor with Needles, ULTRATAPE◊ (Blue);
HEALICOIL◊ PK Suture Anchor with Needles, ULTRATAPE◊ (Blue Cobraid)

Indications for Use *(Describe)*
The HEALICOIL◊ PK Suture Anchor with Needles, ULTRATAPE◊ (Blue) and HEALICOIL◊ PK Suture Anchor with Needles, ULTRATAPE◊ (Blue Cobraid) are 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

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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Smith+Nephew

510(k) Summary

Prepared: 03 August 2023

Submitter Information	Contact Information
Smith & Nephew, Inc. Endoscopy Division 150 Minuteman Road Andover, MA 01810	Mrs. Camille Fleischer Senior Regulatory Affairs Specialist Phone: (978) 749-1057

Device Name & Classification	
Proprietary Name	HEALICOIL° PK Suture Anchor with Needles, ULTRATAPE° (Blue) HEALICOIL° PK Suture Anchor with Needles, ULTRATAPE° (Blue Cobraid)
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 HEALICOIL° PK Suture Anchor with Needles, ULTRATAPE° (Blue) and HEALICOIL° PK Suture Anchor with Needles, ULTRATAPE° (Blue Cobraid) is substantially equivalent in intended use and fundamental scientific technology to the following legally marketed devices in commercial distribution:

Description	Submission Number	Clearance Date
HEALICOIL PK Suture Anchor	K152566	02DEC2015

Legally Marketed Reference Devices

Description	Submission Number	Clearance Date
TWINFIX Ti 3.5 Suture Anchor with two ULTRABRAID Sutures #2 and Needles, SL	K123425	20FEB2013
FAST-FIX FLEX	K203393	01FEB2021

Device Description

The Smith & Nephew HEALICOIL° PK Suture Anchor with Needles, ULTRATAPE° (Blue) and HEALICOIL° PK Suture Anchor with Needles, ULTRATAPE° (Blue Cobraid) is a fixation device intended to provide reattachment of soft tissue to bone. The device consists of a suture anchor with a preloaded ULTRATAPE° suture with needles assembled on an insertion device.

Intended Use

The HEALICOIL° PK Suture Anchor with Needles, ULTRATAPE° (Blue) and HEALICOIL° PK Suture Anchor with Needles, ULTRATAPE° (Blue Cobraid) is intended for use for the reattachment of soft tissue to bone.

Indications for Use

The HEALICOIL° PK Suture Anchor with Needles, ULTRATAPE° (Blue) and HEALICOIL° PK Suture Anchor with Needles, ULTRATAPE° (Blue Cobraid) are 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

Technological Characteristics

The change is modifying the design of the Smith & Nephew HEALICOIL PK Suture Anchor (K152566) to include a new inserter and the addition needles to the preloaded ULTRATAPE suture. The Smith & Nephew HEALICOIL° PK Suture Anchor with Needles, ULTRATAPE° (Blue) and HEALICOIL° PK Suture Anchor with Needles, ULTRATAPE° (Blue Cobraid) is similar in intended use, indications for use, materials, design, and manufacturing process as the predicate; some of the same components as the reference device TWINFIX Ti 3.5 Suture Anchor with two ULTRABRAID Sutures #2 and Needles, SL (K123425) and the same packaging configuration as the reference device FAST-FIX FLEX (K203393) will be used. HEALICOIL° PK Suture Anchor with Needles, ULTRATAPE° (Blue) and HEALICOIL° PK Suture Anchor with Needles, ULTRATAPE° (Blue Cobraid) are substantially equivalent the predicate. The differences between the proposed device and predicate device are considered minor and do not raise new questions of safety or effectiveness.

Performance Data

Mechanical testing performed on the device and all components met the required specifications for the completed tests. A summary of the test results has been provided for fixation, insertion & fixation, cyclic loading and needle attachment. The results for all testing were passing.

Conclusion

The substantial equivalence of the HEALICOIL® PK Suture Anchor with Needles, ULTRATAPE® (Blue) and HEALICOIL® PK Suture Anchor with Needles, ULTRATAPE® (Blue Cobraid) is based on similarities in indications for use, design features, operational principles, material biocompatibility and composition. Modifications in design are minor and do not raise additional questions of safety or effectiveness compared to the predicate device. Based on the similarities the HEALICOIL® PK Suture Anchor with Needles, ULTRATAPE® (Blue) and HEALICOIL® PK Suture Anchor with Needles, ULTRATAPE® (Blue Cobraid) is substantially equivalent to the predicate.