Smith & Nephew, Inc.
Camille Black
Regulatory Affairs Specialist II
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

March 18, 2020

Re: K193558
Trade/Device Name: HEALICOIL Knotless Suture Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: MAI, MBI
Dated: December 20, 2019
Received: December 23, 2019

Dear Camille Black:

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,

For; Laurence Coyne
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193558

Device Name
HEALICOIL Knotless Suture Anchor

Indications for Use *(Describe)*
The Smith & Nephew HEALICOIL Knotless Suture Anchor is intended for use only for the reattachment of soft tissue to bone for the following indications:

Shoulder
• Biceps tenodesis
• Rotator cuff tear 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.

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Smith+Nephew

510(k) Summary

Prepared: 05 March 2020

Submitter Information	Contact Information
Smith & Nephew, Inc. Endoscopy Division 150 Minuteman Road Andover, MA 01810	Camille Black Regulatory Affairs Specialist II Phone: (978) 749-1057 Fax: (978) 749-1443

Device Name & Classification	
Proprietary Name	HEALICOIL® Knotless Suture Anchor
Common Name	Soft Tissue Fixation Device
Classification Name	Fastener, fixation, biodegradable, soft tissue; fastener, fixation, nondegradable, soft tissue
Classification Regulation	21 CFR 888.3030 ; 21 CFR 888.3040
Class	II
Product Code(s)	MAI; MBI
Panel	Orthopedic

Legally Marketed Predicate Devices

The Smith & Nephew HEALICOIL Knotless 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
FOOTPRINT PK FP Suture Anchor	K073509	04 MAR 2008
HEALICOIL REGENESORB Suture Anchor	K123393	11 APR 2013
TWINFIX Ultra Ti Suture Anchor	K100159	19 APR 2010

Legally Marketed Reference Devices

Description	Submission Number	Clearance Date
MICRORAPTOR Knotless Suture Anchor	K181746	28 SEP 2018
BIORAPTOR 2.3 PK Suture Anchor	K071586	17 AUG 2007

Device Description

The HEALICOIL Knotless Suture Anchor consists of an anchor on an inserter fitted with a suture passer. The anchor consists of the following components: a proximal implant (REGENESORB or PEEK), a non-absorbable distal implant (PEEK or Titanium), and a non-absorbable PEEK plug. The anchor is preloaded on a stainless steel inserter. This device is to be used with Smith & Nephew ULTRABRAID, ULTRATAPE, and MINITAPE Sutures. This device is provided sterile, for single use only.

Intended Use

The Smith & Nephew HEALICOIL Knotless Suture Anchor is intended for use only for the reattachment of soft tissue to bone for the following indications:

Shoulder

- Biceps tenodesis
- Rotator cuff tear repair

Technological Characteristics

The Smith & Nephew HEALICOIL Knotless Suture Anchor is substantially equivalent in intended use and fundamental scientific technology as the legally marketed primary predicate device – the Smith & Nephew FOOTPRINT PK Suture Anchor (K073509) and the additional predicates – the Smith & Nephew HEALICOIL REGENESORB Suture Anchor (K123393) and the Smith & Nephew TWINFIX Ultra Ti Suture Anchor (K100159), and raise no new questions of safety and efficacy. The Smith & Nephew HEALICOIL Knotless Suture Anchor and the predicate devices use identical implant materials.

Summary Performance Data

Sterilization of the HEALICOIL Knotless Suture Anchor was compared to the predicate HEALICOIL REGENESORB Suture Anchor (K123393). Shelf-life of the HEALICOIL Knotless Suture Anchor was based on the configurations of the predicate HEALICOIL REGENESORB Suture Anchor (K123393) and reference devices MICRORAPTOR Knotless Suture Anchor (K181746) and BIORAPTOR 2.3 PK Suture Anchor (K071586). Bacterial endotoxin testing was completed and met acceptable endotoxin limits per ANSI/AAMI ST72:2011.

The biocompatibility of the HEALICOIL Knotless Suture Anchor was evaluated against the requirements per ISO 10993-1:2018. All acceptance criteria were met.

The performance data demonstrates that the HEALICOIL Knotless Suture Anchor had met performance specifications for insertion strength and pull-out strength. The HEALICIOL Knotless Suture Anchor met performance specifications for cyclic loading based on the primary predicate FOOTPRINT PK Suture Anchor (K073509).

Therefore, the HEALICOIL Knotless Suture Anchor is considered substantially equivalent to the currently marketed predicates.

Substantial Equivalence Information

The substantial equivalence of the HEALICOIL Knotless Suture Anchor is based on similarities in indications for use, design features, operational principles, material biocompatibility and composition, and performance to the predicate devices listed above. Based on the similarities to the predicates, the HEALICOIL Knotless Suture Anchor is equivalent to its predicates.