October 27 2026

Smith & Nephew, Inc.
Amanda Cole
Sr. Regulatory Affairs Specialist
150 Minuteman Rd.
Andover, Massachusetts 01810

Re: K263461
Trade/Device Name: Tendon Anchor
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW, HXJ
Dated: September 28, 2026
Received: September 28, 2026

Dear Amanda Cole:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

TEK N. LAMICHHANE -S

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive Surgery Devices
OHT4: Office of Surgical and
Infection Control 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.

510(k) Number *(if known)*
K263461

Device Name
Tendon Anchor

Indications for Use *(Describe)*
The Tendon Anchor is indicated for fixation of the REGENETEN◊ Bioinductive Implant to soft tissues in various minimally invasive and open surgical procedures, such as the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
K263461

510(k) SUMMARY COMPLYING WITH 21 CFR 807.92

Date Prepared:	October 26, 2026
Submitter Name:	Smith & Nephew, Inc.
Submitter Address:	150 Minuteman Road Andover, MA 01810
FDA Establishment Owner/Operator Number:	1020279
FDA Establishment Registration Number:	3003604053
Submitter / Primary Contact:	Amanda Cole Sr. Regulatory Affairs Specialist (978) 809-5016 Email: Amanda.Cole2@smith-nephew.com
Alternate Contact:	Michael Secondini Regulatory Affairs Director (508) 261-3713 Michael.Secondini@smith-nephew.com
Device Trade / Proprietary Name:	Tendon Anchor
Device Common Name:	Implantable staple
Device Classification Name:	Staple, Implantable
Regulation Medical Specialty:	Office of General & Plastic Surgery
Review Panel(s):	Office of General & Plastic Surgery
Product Code(s):	GDW, HXJ
Regulation Numbers:	21 CFR 878.4750
Submission Type:	Special 510(k)
Device Class:	Class II
Device Predicate:	Rotation Medical Soft Tissue Staple (RMST Staple) (K131637)

Device Description:

The Smith & Nephew Tendon Anchor is an absorbable polymer anchor with cleat tips. The Tendon Anchor is composed of an absorbable synthetic polyester derived from lactic acid and dyed with D&C Violet #2. The Smith & Nephew Tendon Anchor is used in conjunction with an orthopedic manual staple driver; a Class I exempt device pursuant to 21 CFR 888.4540 and is not the subject of this submission.

Intended Use:

The Tendon Anchor is a medical device intended for fixation of the REGENETEN◊ Bioinductive Implant to soft tissues.

Indications for Use:

The Tendon Anchor is indicated for fixation of the REGENETEN◊ Bioinductive Implant to soft tissues in various minimally invasive and open surgical procedures, such as the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

Substantive Equivalence and Comparison of Technical Characteristics:

The Smith & Nephew Tendon Anchor (subject device) has the same intended use and indications for use and is comprised of the same materials as the RMST Staple (predicate device). Due to slight differences in dimensional specification, the Smith & Nephew Tendon Anchor (subject device) performance was evaluated for retention strength and tensile strength. The packaging configuration has been evaluated for stability and integrity to demonstrate substantial equivalence to the predicate device.

The substantial equivalence of the Smith & Nephew Tendon Anchor is based on similarities in intended use and indications for use, design features, sterilization, operational principles, performance specifications, material composition and biocompatibility. Modifications in dimensional specifications and packaging configuration for the device do not raise additional questions of safety or effectiveness compared to the predicate device.

Performance Data (Bench Testing):

The Smith & Nephew Tendon Anchor was subjected to mechanical testing for retention strength and tensile strength with passing results. Packaging stability and integrity studies demonstrated that the packaging configuration is sufficient to protect the device over its labeled shelf life.

Conclusion:

Based on the similarities, the Tendon Anchor is substantially equivalent to the predicate device (RMST Staple, K131637).