November 26, 2024

Smith & Nephew Inc., Endoscopy Div.
Lacey Klungseth
Pr. Regulatory Affairs Specialist
150 Minuteman Road
Andover, Massachusetts 01810

Re: K242631
Trade/Device Name: REGENETEN™ Bioinductive Implant
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWY, ORQ
Dated: August 28, 2024
Received: September 3, 2024

Dear Lacey Klungseth:

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.

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, MS
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)*
K242631

Device Name
REGENETEN™ Bioinductive Implant

Indications for Use *(Describe)*

The REGENETEN Bioinductive* Implant is indicated for the management and protection of tendon or extra-articular ligament injuries in which there has been no substantial loss of tendon or ligament tissue.
* Bioinductivity has been demonstrated for tendon only.

The REGENETEN Bioinductive Implant Delivery System is indicated for the arthroscopic delivery of the REGENETEN Bioinductive Implant.

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

K242631

Attachment 15:

510(k) Summary According to 21 CFR 807.92

Date Prepared:	November 8, 2024
Submitter Name & Address:	Smith and Nephew, Inc. Endoscopy 150 Minuteman Road Andover, MA 01810
FDA Establishment Owner/Operator Number:	1020279
FDA Establishment Registration Number:	3003604053
Submitter / Primary Contact:	Lacey Klungseth Pr. Regulatory Affairs Specialist (612) 443-2734 Lacey.Klungseth@Smith-Nephwe.com
Alternate Contact:	Jenna Horsley Regulatory Affairs Director (617) 218-7921 Jenna.Horsley@smith-nephew.com
Device Trade / Proprietary Name:	REGENETEN™ Bioinductive Implant
Device Common Name:	Surgical mesh
Device Classification Name:	Mesh, Surgical, Collagen, Orthopaedics
Regulation Medical Specialty:	Office of General & Plastic Surgery
Review Panel(s):	Office of General & Plastic Surgery
Product Code(s):	OWY (Bioinductive Implant), ORQ (Bioinductive Implant Delivery Instrument)
Regulation Numbers:	21 CFR 878.3300
Submission Type:	Traditional 510(k)
Device Class:	Class II
Device Predicate:	REGENETEN™ Bioinductive Implant (K222501)

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Device Description:

The REGENETEN™ Bioinductive Implant is a bioabsorbable implant device that provides a layer of collagen over injured tendons or ligaments. The implant is designed to provide a layer of collagen between a tendon or ligament and the surrounding tissue. After hydration, the implant is an easy-to-handle, pliable, nonfriable, porous collagen sheet. The REGENETEN Bioinductive Implant is provided sterile, non-pyrogenic, for single-use only, in a variety of sizes, in a dual sterile seal.

Proposed Intended Use

The REGENETEN™ Bioinductive* Implant is a medical device intended for the management and protection of soft tissue injuries, including tendon *and extra-articular ligament*.

Proposed Indications for Use

The REGENETEN™ Bioinductive Implant is indicated for the management and protection of tendon *or extra-articular ligament* injuries in which there has been no substantial loss of tendon *or ligament* tissue.
* Bioinductivity has been demonstrated for tendon only.

The REGENETEN™ Bioinductive Implant Delivery System is indicated for the arthroscopic delivery of the REGENETEN™ Bioinductive Implant.

Summary of Technological Characteristics Compared to Predicate Device:

The subject device (REGENETEN Bioinductive Implant) and the predicate device (REGENETEN Bioinductive Implant, K222501), are identical devices, having the same physical performance characteristics, packaging, and material composition. Past safety, bench testing, and animal study of the predicate device are directly applicable to the subject device. Previous verification testing completed is directly applicable to the subject device, including staple pull-out testing, hydrothermal transition temperature, endotoxin testing, and mechanical integrity.

The subject device has identical technological characteristics as the predicate device with the addition of the expanded indication. The expanded indications for use did not require any change in the device design, material composition, and packaging and this technological difference is supported by, valid, reproducible performance testing.

Biocompatibility:

The subject device (REGENETEN Bioinductive Implant) and the predicate device (REGENETEN Bioinductive Implant, K222501) are physically identical devices; therefore, additional biocompatibility testing is not required to support this submission.

Performance Data (Bench Testing):

The Regeneten Bioinductive Implant is identical to the predicate device (REGENETEN Bioinductive Implant, K222501) and performance specifications are identical. Past safety, verification, and mechanical characterization tests of the predicate device are directly applicable to the subject device, including staple pull-out testing, hydrothermal transition temperature, endotoxin testing, and mechanical integrity.

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Performance Data (Animal Testing):

Smith and Nephew conducted an animal study with multiple timepoints evaluating the REGENETEN Bioinductive Implant in an *in vivo* ovine bilateral model with a primary histology endpoint to demonstrate ligament-like tissue formation post-capsulotomy.

A direct comparative analysis between sutured repair (control group) and sutured repair with Bioinductive Implant (treatment group) evaluated healing progression, formation of neo-tissue, and resemblance to native tissue. Results show the Bioinductive Implant results in increased ligament thickness and that the Bioinductive Implant can be safely implanted for ligament repair without raising any new issues of safety and effectiveness.

Bioinductivity has been demonstrated for tendon only.

Compliance to Standards:

This submission does not claim compliance to any new FDA recognized consensus standards.

Substantial Equivalence and Conclusion:

No design modifications were completed regarding the expanded indications for use and the subject device (REGENETEN Bioinductive Implant) is identical to the predicate device (REGENETEN Bioinductive Implant, K222501) in terms of material composition, design, packaging, sterilization, and biocompatibility. The only difference is the addition of ligament tissue to the indications for use.

Expansion of indications for use to include management and protection of extra-articular ligament injuries does not impact the intended surgical purpose of the device, nor does it affect the safety and efficacy of the device relative to the predicate. Both the subject and predicate devices have the same intended surgical purpose.

This difference is substantiated by reviewing the results of the animal study presented in this 510(k). Based on the comparative analysis, the REGENETEN Bioinductive Implant has been shown to be substantially equivalent to its predicate, the REGENETEN Bioinductive Implant (K222501). They are the same device: the technological characteristics, packaging, and sterilization parameters are identical. Only the indications for use have changed.