Smith and Nephew Inc
Jenna Horsley
Senior Regulatory Affairs Manager
150 Minuteman Road
Andover, Massachusetts 01810

Re: K222501
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: April 11, 2023
Received: April 11, 2023

Dear Jenna Horsley:

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,

Yu-chieh Chiu -S

Digitally signed by Yu-chieh Chiu -S
Date: 2023.05.11 15:47:39 -04'00'

Yu-Chieh Chiu
Acting Assistant Director
DHT6C: Division of Stereotaxic, Trauma and Restorative 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)*
K222501

Device Name
Regeneten Bioinductive Implant

Indications for Use *(Describe)*
Regeneten Bioinductive Implant is indicated for 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.

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5. 510(k) Summary

510(k) SUMMARY COMPLYING WITH 21 CFR 807.92

Date Prepared:	April 11, 2022
Submitter Name:	Smith and Nephew Inc
Submitter Address:	150 Minuteman Road Andover, MA 01810
FDA Establishment Owner/Operator Number:	1020279
FDA Establishment Registration Number:	3003604053
Submitter / Primary Contact:	Jenna Horsley Senior Regulatory Affairs Manager (617) 218-7921 Jenna.Horsley@smith-nephew.com
Alternate Contact:	Hamed Rahimi Regulatory Affairs Specialist (636) 628-6500 Email: hamed.rahimi@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, ORQ
Regulation Numbers:	21 CFR 878.3300
Submission Type:	Traditional 510(k)
Device Class:	Class II
Device Predicate:	Rotation Medical Collagen Tendon Sheet (K140300)

Device Description:

Regeneten Bioinductive Implant is a resorbable type I bovine Achilles-derived collagen implant that provides a layer of collagen over injured tendons. The device is designed to provide a layer between the tendon and the surrounding tissue during healing. The device features a large porosity design with a low tensile modulus to allow for recipient tissue ingrowth into the implant at the repair site for natural remodeling and the passive formation of collagen over injured tendons. The physical structure and placement of Regeneten Bioinductive Implant provides and supports an environment for healing. When hydrated, Regeneten Bioinductive Implant is an easy-to-use, soft, pliable, nonfriable, porous implant. Regeneten Bioinductive Implant is provided as a sterile, single-use device in a variety of sizes. The arthroscopic configuration of the Bioinductive implant is preloaded in a cartridge and packaged in a sterile, dual seal tray-in-tray configuration.

Intended Use:

The subject device and predicate device have the same intended use:

The Regeneten Bioinductive Implant is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

Indications for Use:

The subject device has the same indication for use as the predicate device:

The Regeneten Bioinductive Implant is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

Summary of Technological Characteristics Compared to Predicate Device(s):

The subject device (Regeneten Bioinductive Implant) and the predicate device (Rotation Medical Collagen Tendon Sheet-DDI, K140300), 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 similar technological characteristics as the predicate device with the addition of performance claims of bioinduction, formations of tendon-like tissue, and change the course of tear progression (see the performance claims table in the device description section). The addition of this performance claim 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 (Rotation Medical Collagen Tendon Sheet-DDI, K140300) are identical devices. Therefore, past biocompatibility tests included in 510(k) K112423 are applicable to the subject device. Routine monitoring of endotoxin is being performed for every production batch as part of the finished product release process.

Performance Data (Bench Testing):

The Regeneten Bioinductive Implant is identical to the predicate device (Rotation Medical Collagen Tendon Sheet-DDI) 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.

Performance Data (Animal Testing):

Results of the original animal study submitted as part of 510(k) K112423 and K140300 is applicable to the subject device since the subject device and the predicate device have identical indication for use, design, material composition, packaging, and sterilization. Animal study histological results presented in this submission support the performance claims of bioinduction and formation of tendon-like tissue of the predicate device.

Performance Data (Clinical Study):

No clinical study was conducted for the predicate device and a clinical study was not required to substantiate new performance claims for the subject device. Published clinical literature from investigator-initiated post-market clinical studies was reviewed in this submission in support of new performance claims for the subject device.

Compliance to Standards:

This submission does not include any performance or preclinical testing and therefore, is not claiming compliance to any new FDA recognized consensus standards.

Substantial Equivalence and Conclusion:

No design modifications were necessary to support the additional performance claims and the subject device (Regeneten Bioinductive Implant) is identical to the predicate device (Rotation Medical Collagen Tendon Sheet-DDI, K140300) in terms of material composition, design, packaging, sterilization, and biocompatibility. The only difference is the addition of performance claims of bioinduction, formation of tendon-like tissue, and change the course of tear progression to the subject device. This difference is substantiated by reviewing the results of the animal study in section 19 and presenting clinical study results from the post-market clinical studies in section 20. Based on the comparative analysis, Regeneten Bioinductive Implant is substantially equivalent to its predicate, Collagen Tendon Sheet-DDI; they are the same device, only with the addition of performance claims of bioinduction,

formation of tendon-like tissue, and change the course of tear progression have has been added to the subject device.