February 27, 2025

Nanofiber Solutions, LLC
Jason Chakroff
QA/RA Manager
5164 Blazer Parkway
Dublin, Ohio 43017

Re: K250021
Trade/Device Name: Rotium
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OWW
Dated: January 2, 2025
Received: January 3, 2025

Dear Jason Chakroff:

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,

Thomas Mcnamara -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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250021

Device Name
Rotium®

Indications for Use *(Describe)*
Rotium® 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) Summary

SUBMITTER'S INFORMATION

Owner: Nanofiber Solutions, LLC

Address: 5164 Blazer Parkway
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Official Correspondent: Jason T. Chakroff
614-565-4161
jason.chakroff@nanofibersolutions.com

Date Summary Prepared: February 27, 2025

DEVICE INFORMATION

Name of Device: Rotium®

Common/Usual Name: Surgical Mesh

Classification Name: Surgical Mesh (21 CFR 878.3300)

Regulatory Class: Class II

Product Code: OWW

Predicate Device(s): TAPESTRY Biointegrative Implant (K201572)

Reference Device(s): Rotium Bioresorbable Wick (K183236, K201414, K231641)

Reason for Submission: New Device

Indication for Use: Rotium® is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

Device Description: Rotium® is composed of two types of polymer fibers: Poly(lactide-co-caprolactone) (PLCL) and Polyglycolic acid (PGA). It is designed to function as a non-constricting, protective layer between the tendon and surrounding tissues. Rotium® is conformable and designed for easy placement between the tendon and surrounding tissue and may be secured in place using standard fixation techniques. Rotium® is provided sterile, non-pyrogenic, for single-use only, in a variety of sizes, ranging from 20mm x 20mm to 70mm x 25mm. Rotium® is designed for stand-alone use. At the discretion of the surgeon, Rotium® may be hydrated with sterile isotonic solution.

Technological Characteristics: Rotium® has very similar technological characteristics compared to the predicate, TAPESTRY Biointegrative Implant (K201572). Physical and mechanical properties such as materials, construction, size, thickness, and suture retention are similar between the products.

510(K) Summary

Performance Data: Biocompatability

Rotium® has been tested according to ISO 10993, *Biological Evaluation of Medical Devices.* The following testing was conducted: Cytotoxicity, Intracutaneous Reactivity, Sensitization, Acute Systemic Toxicity, 20 Week Systemic Toxicity, 4-Week Implantation, 8-Week Implantation, 20-Week Implantation, Genotoxicity and Pyrogenicity. Rotium® was found to be non-cytotoxic, nonirritating and non-sensitizing. Rotium® exhibited no systemic toxicity. It was non-pyrogenic and non-mutagenic.

Bench Testing

The following tests were conducted to demonstrate substantial equivalence to the predicate device: dimensional analysis, density, tensile strength, strain at break, flexibility, and suture retention strength.

Animal Testing

Rotium® was evaluated in a rabbit calcaneal tendon injury model. Histological analysis confirmed that the use of Rotium® did not introduce any new safety or effectiveness issues.

Substantial Equivalence: Rotium® is substantially equivalent to the TAPESTRY Biointegrative Implant (K201572). Rotium® raises no new questions of safety or effectiveness as compared to the predicate devices. Rotium® has the same intended use and indications for use, technological characteristics, and principles of operation as the predicate devices. There are no new novel features as compared to the Tapestry predicate device.

Conclusion: The information in this submission demonstrates that the subject device is substantially equivalent to the cited predicate device. The non-clinical data support the safety and effectiveness of the device and demonstrate that Rotium® should perform as intended in the specified use conditions.