July 5, 2023

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

Re: K231641
Trade/Device Name: Rotium Bioresorbable Wick
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: MAI
Dated: May 31, 2023
Received: June 5, 2023

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 (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,

Jesse Muir -S

Jesse Muir, Ph.D.
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)*
K231641

Device Name
Rotium™ Bioresorbable Wick

Indications for Use *(Describe)*
The Rotium™ Bioresorbable Wick is intended to be used in conjunction with suture anchors for the reattachment of tendon to bone in rotator cuff repairs.

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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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(K) Summary

K231641

## SUBMITTER'S INFORMATION


**Owner:** Nanofiber Solutions, LLC

**Address:** 5164 Blazer Parkway
Dublin, OH 43017

**Official Correspondent:** Jason T. Chakroff
614-565-4161
jason.chakroff@nanofibersolutions.com


**Date Summary Prepared:** May 31, 2023

## DEVICE INFORMATION

**Name of Device:** Rotium™ Bioresorbable Wick

**Common/Usual Name:** Bioresorbable Wick Accessory

**Classification Name:** Fastener, fixation, biodegradable, soft tissue fixation appliances and accessories (21 CFR 888.3030)

**Regulatory Class:** Class II

**Product Code:** MAI

**Primary Predicate Device:** Rotium™ Bioresorbable Wick, K183236, K201414

**Reason for Submission:** Updating labeling to allow for placement on top of the rotator cuff tendon.

**Indication for Use:** The Rotium™ Bioresorbable Wick is intended to be used in conjunction with suture anchors for the reattachment of tendon to bone in rotator cuff repairs.

**Device Description:** The Rotium™ Bioresorbable Wick is an accessory to be used in conjunction with suture anchors for rotator cuff repair. The wick is placed over the tendon and is designed to facilitate tendon-bone reattachment. The wick is an electrospun, non-woven, microporous, microfiber matrix. The wick is made from two types of polymer fibers: Poly(lactide-co-caprolactone) (PLCL) and Polyglycolic acid (PGA). The wick is packaged in a primary foil pouch with a desiccant pouch, sealed within a secondary Tyvek pouch. The device is supplied gamma-sterilized. The device is single use only.

# 510(K) Summary

**Technological Characteristics:** No changes have been made to the technological characteristics of the device.

**Performance Data:** No new performance data is required because the labeling changes made to the device will have no impact on the Biocompatibility, Bench Testing, or Animal Testing results of the predicate (K183236, K201414).

**Substantial Equivalence:** The Rotium™ Bioresorbable Wick accessory is identical to the predicate, Rotium™ Bioresorbable Wick (K183236, K201414). The labeling changes raise no new safety or effectiveness questions.

**Conclusion:** The Rotium™ Bioresorbable Wick accessory is substantially equivalent to the primary predicate device.