June 25, 2020

Nanofiber Solutions, LLC
Jason Chakroff
Project Engineer
4389 Weaver Ct. N.
Hilliard, Ohio 43026

Re: K201414
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 27, 2020
Received: May 29, 2020

Dear Mr. 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,

for

Laura Rose, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201414

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)

510(K) Summary

SUBMITTER'S INFORMATION

Owner: Nanofiber Solutions, LLC

Address: 4389 Weaver Court North
Hilliard, OH 43026

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

Date Summary Prepared: June 12, 2020

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

Reason for Submission: Updating the list of suture and anchor devices that are compatible with the wick accessory.

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 between the bone and the tendon and is designed to facilitate tendon-bone attachment. 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.

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

510(K) Summary

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). Material mediated pyrogenicity testing has demonstrated that the device is non-pyrogenic. The Rotium™ Bioresorbable Wick was also tested for the presence of endotoxin via the LAL kinetic chromogenic method. Test results indicate the endotoxin levels were below the recommended limit of 20 EU/device.

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

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