March 11, 2019

Nanofiber Solutions, LLC
Ronald L. Bracken
Chief Operating Officer
4389 Weaver Court North
Hilliard, Ohio 43026

Re: K183236
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: February 7, 2019
Received: February 8, 2019

Dear Mr. Bracken:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurence D. Coyne -S

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K183236

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.

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510(K) Summary

SUBMITTER'S INFORMATION

Owner: Nanofiber Solutions, LLC

Address: 4389 Weaver Court North
Hilliard, OH 43026

Official Correspondent: Ronald L. Bracken
770-597-7656
ronny.bracken@nanofibersolutions.com

Date Summary Prepared: February 7, 2019

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

Predicate Device(s): BioWick™ X Implant with Driver, K172186

Reason for Submission: New Device

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 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: The Rotium™ Bioresorbable Wick accessory when utilized in conjunction with suture anchors has very similar technological characteristics compared to the predicate, BioWick™ X Implant with Driver (K172186). Physical and mechanical properties such as wick materials, wick construction, wick thickness, wick density and wick retention are similar between the products.

Performance Data: Biocompatability

The Rotium™ Bioresorbable Wick has been tested according to ISO 10993, *Biological Evaluation of Medical Devices.* The following testing was conducted: Cytotoxicity, Intracutaneous Reactivity, Sensitization, Acute Systemic Toxicity, 12 Week Systemic Toxicity, 4-Week Muscle Implantation, 8-Week Muscle Implantation, 12-Week Muscle Implantation, Genotoxicity and Pyrogenicity. The Rotium™ Bioresorbable Wick was found to be non-cytotoxic, nonirritating and non-sensitizing. The Rotium™ Bioresorbable Wick exhibited no systemic toxicity. It was non-pyrogenic and non-mutagenic. 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.

Bench Testing

The following test were conducted to demonstrate substantial equivalence to the predicate device's wick: dimensional analysis, density, tensile strength, strain at break, flexibility, suturability, cannula compatibility and wick retention strength.

Animal Testing

The Rotium™ Bioresorbable Wick accessory used in conjunction with suture anchors was evaluated in an ovine rotator cuff model. Biomechanical testing and histological analysis confirmed that the use of the Rotium™ bioresorbable wick did not introduce any new safety or effectiveness issues.

Substantial Equivalence: The Rotium™ Bioresorbable Wick accessory when utilized in conjunction with suture anchors is substantially equivalent to the BioWick™ X Implant with Driver (K172186). The Rotium™ Bioresorbable Wick accessory raises no new questions of safety or effectiveness as compared to the predicate devices. The Rotium™ Bioresorbable Wick 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 BioWick X predicate device. The minor differences regarding placement of the bioresorbable wick and wick retention between the Rotium™ device and its predicate device raise no new issues of safety or effectiveness.

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™ Bioresorbable Wick should perform as intended in the specified use conditions.