July 29, 2024

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

Re: K241912
Trade/Device Name: BIOCHARGE
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: July 1, 2024
Received: July 1, 2024

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.

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,

Christopher Ferreira -S

for

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241912

Device Name
BIOCHARGE™

Indications for Use *(Describe)*
BIOCHARGE™ 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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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: July 23, 2024

DEVICE INFORMATION

Name of Device: BIOCHARGE™

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, K231641

Reference Device: Rotium® Bioresorbable Wick, K183236

Reason for Submission: Design updates to facilitate suture passage through the device.

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

Device Description: BIOCHARGE™ is a bioresorbable wick accessory to be used in conjunction with suture anchors for rotator cuff repair. BIOCHARGE is placed over the tendon and is designed to facilitate tendon-bone reattachment. BIOCHARGE is an electrospun, non-woven, microporous, microfiber matrix. It is made from two types of polymer fibers: Poly(lactide-co-caprolactone) (PLCL) and Polyglycolic acid (PGA). BIOCHARGE 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 device design has been updated to include a pre-built pathway for suture passage through the device. No other changes have been made to the technological characteristics of the device.

Performance Data: The updated device has undergone design verification testing to confirm that the design change has no negative impact on bench testing results compared to the predicate. The design change will have no impact on the Biocompatibility or Animal Testing results of the predicate (K231641, K201414, K183236).

Substantial Equivalence: BIOCHARGE™ is substantially equivalent to the predicate, Rotium™ Bioresorbable Wick (K231641, K201414, K183236). The device intended use, indications, environment of use, principles of operation, materials of construction, body contact, packaging, technological characteristics, sterilization, labeling, shelf life, or performance are unchanged. The design change raises no new safety or effectiveness questions.

Conclusion: BIOCHARGE™ is substantially equivalent to the primary predicate device.