November 2, 2023

Alafair Biosciences Inc
Angela Mallery
Regulatory
6101 West Courtyard Drive, Suite 2-225
Austin, Texas 78730

Re: K232029
Trade/Device Name: VersaWrap Nerve Protector
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve Cuff
Regulatory Class: Class II
Product Code: JXI
Dated: October 5, 2023
Received: October 5, 2023

Dear Angela Mallery:

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,

Adam D. Pierce -S
Digitally signed by Adam D. Pierce -S
Date: 2023.11.02 16:14:48 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
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and Physical Medicine 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)*
K232029

Device Name
VersaWrap Nerve Protector

Indications for Use *(Describe)*
VersaWrap Nerve Protector is indicated for the management of peripheral nerve injuries in which there has been no substantial loss of nerve 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.

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510(k) Summary
VersaWrap Nerve Protector
K232029

Submitted by:	Alafair Biosciences, Inc. 6101 W Courtyard Drive Ste. 1-225 Austin, TX 78730 800.206.5586; info@alafairbiosciences.com
Date Prepared:	October 26, 2023
Contact:	Ben Walthall, Ph.D. Chief Regulatory Officer 800.206.5586; info@alafairbiosciences.com
Product Name	VersaWrap Nerve Protector
Common Name	Cuff, Nerve
Classification number	21 CFR 882.5275
Product Code	JXI
Predicate Device:	VersaWrap Nerve Protector K201631
Device Description:	VersaWrap Nerve Protector (VersaWrap) is designed to function as an interface between an injured nerve and surrounding tissues and is indicated for use in peripheral nerve injuries where there is no significant loss of nerve tissue. VersaWrap Nerve Protector is a thin, flexible implant, designed to be a non-constricting gelatinous interface encasing peripheral nerves and the neural environment; that starts to absorb after implant. VersaWrap Nerve Protector is designed to be flexible and conformable for placement around a peripheral nerve.
Indications for Use:	VersaWrap Nerve Protector is indicated for the management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue.
Functional and Safety Testing:	No additional functional or safety testing was required.

Comparative Technological Characteristics

Device Name	VersaWrap	VersaWrap
510(k) #	K232029	K201631
Material	Calcium alginate and hyaluronic acid	Calcium alginate and hyaluronic acid
Intended Use	Designed to be an interface between an injured area and surrounding tissue	Designed to be an interface between an injured area and surrounding tissue
Physical Structure	Sheet	Sheet
Precautions	Do not resterilize. Discard all opened and unused portions of VersaWrap Nerve Protector. Based on in vivo animal studies in a rat sciatic nerve injury model, the VersaWrap Nerve Protector can displace or move after placement on the nerve. Patient mobility should be considered to mitigate the risk of device movement post-implant.	Do not resterilize. Discard all opened and unused portions of VersaWrap Nerve Protector. Intended population. Safety and effectiveness has not been established in pediatric patients. Based on in vivo animal studies in a rat sciatic nerve injury model, the VersaWrap Nerve Protector can displace or move after placement on the nerve. Patient mobility should be considered to mitigate the risk of device movement post-implant.

Conclusion	Based on an assessment of the risks associated with use in a pediatric population and prior animal, in vitro product characterization, in vitro and in vivo biocompatibility, and performance studies, we conclude the device is as safe as, and substantially equivalent to, its predicate device.