July 17, 2025

Alafair Biosciences
Sarah Mayes, Ph.D.
Chief Scientific Officer
6101 W. Courtyard Drive, Suite 1-225
Austin, Texas 78730

Re: K251175
Trade/Device Name: VersaWrap Nerve Protector (VTP-2201); VersaWrap Nerve Protector (VTP-1201)
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve Cuff
Regulatory Class: Class II
Product Code: JXI
Dated: June 27, 2025
Received: June 30, 2025

Dear Dr. Mayes:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 2025.07.17 14:49:56 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251175

Please provide the device trade name(s).

VersaWrap Nerve Protector (VTP-2201);
VersaWrap Nerve Protector (VTP-1201)

Please provide your Indications for Use below.

VersaWrap Nerve Protector is indicated for the management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue.

Please select the types of uses (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
Alafair Biosciences, Inc.
6101 W Courtyard Dr Ste 1-225
Austin, TX 78730

Phone: 512.739.9510
Email: info@alafairbiosciences.com

Contact Person: Sarah Mayes
Date Prepared: July 16, 2025

Device
Name of Device: VersaWrap Nerve Protector
Common Name: Cuff, Nerve
Classification Number: 21 CFR 882.5275
Product Code: JXI

Predicate Device
VersaWrap Nerve Protector, K232029

Device Description
VersaWrap Nerve Protector 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 implantation. VersaWrap Nerve Protector is designed to be flexible and conformable for placement on or around a peripheral nerve

Indication 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.

Technology Comparison
The subject and predicate devices are based on the following same technological elements:

- Materials of construction (i.e., material type, material formulation, chemical composition, and material processing)
- Mechanism of action - both the subject and predicate device provide a gliding surface and keep tissues physically separated during healing
- Target population - both the subject and predicate device are intended for use in peripheral nerve injuries

The following technological differences exist between the subject and predicate devices:

- Application method - the subject device is implanted as a gel, the predicate device is implanted as a sheet

Nonclinical Tests Summary & Conclusions
Based on the risk-based assessment, non-clinical testing was conducted to support the determination of substantial equivalence. The data demonstrated that the subject device is substantially equivalent to the predicate device. The following performance data were provided in support of the substantial equivalence determination.

Animal Study

In the animal study conducted, rats underwent various peripheral nerve injuries that received either the subject or predicate device. There were no procedure related complications or device related premature deaths in this study, at all follow-up timepoints. The safety and efficacy of the subject device were evaluated by neurological assessment, and macroscopic and histological evaluation. These studies demonstrate that the subject device can safely provide an interface between injured nerve and surrounding tissues, without device migration, permitting normal axonal survival and growth in a variety of clinically relevant nerve injury models, performing similar to the predicate device.

Bench Studies

Performance of the subject device was demonstrated in bench evaluation and a clinically relevant cadaver model. The battery of performance testing included the following:

- Visual inspection
- Dimensional and weight measurements
- Gel integrity measurements (visual inspection, viscosity, cohesivity)
- Handling
- Coverage testing
- Migration testing
- Cadaveric evaluation

Substantial Equivalence Discussion

The additional application method in the labeling is to allow end users the ability to apply the device as a gel to support device placement. This change is not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device because the difference does not affect the safety and effectiveness of the device when used as labeled, and does not describe a new disease, condition, or patient population. The risk-based assessment did not identify any new risks or significantly modified existing risks. Therefore, the subject device is substantially equivalent to the predicate device.