September 14, 2020

Alafair Biosciences, Inc.
% Angela Mallery
Regulatory Consultant
NAMSA
400 Highway 169 South, Suite 500
Minneapolis, Minnesota 55426

Re: K201631
Trade/Device Name: VersaWrap Nerve Protector
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve Cuff
Regulatory Class: Class II
Product Code: JXI
Dated: June 12, 2020
Received: June 16, 2020

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 (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,

Adam Pierce, Ph.D.
Assistant Director (Acting)
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

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)*
K201631

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
K201631

Submitted by:	Alafair Biosciences, Inc. 6101 W Courtyard Drive Ste. 2-225 Austin, TX 78730 800.206.5586; info@alafairbiosciences.com
Date Prepared:	September 8, 2020
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
Primary Predicate:	Integra NeuraWrap Nerve Protector K041620
Reference Device:	Alafair VersaWrap Tendon Protector K200311
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:	Biocompatibility studies demonstrated the Nerve Protector is non-cytotoxic, non-pyrogenic, non-irritating, non-sensitizing, non-toxic, and non-genotoxic. Animal studies demonstrated the device performed as labeled.
Comparative Technology Characteristics:	

Parameter	Device	Predicate Device	Reference Device
Device name	VersaWrap	NeuraWrap	VersaWrap
Company Name	Alafair Biosciences	Integra Lifesciences	Alafair Biosciences
510(k) #	K201631	K041620	K200311
Material	Calcium alginate and hyaluronic acid	Type 1 bovine collagen and chondroitin-6-sulfate	Calcium alginate and hyaluronic acid

	Intended Use	designed to be an interface between the injured area and the surrounding tissue	designed to be an interface between the injured area and the surrounding tissue	designed to be an interface between the injured area and the surrounding tissue
	Packaging	Double Pouch	Double Pouch	Double Pouch
	Physician Structure	Sheet	Tube	Sheet
	Sterilization Method	eBeam	EO	eBeam

Non-Clinical Tests Performed:

Testing was conducted. The specific conclusions drawn from the testing is that the testing demonstrates the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.

Test/Purpose	Test Method Summary	Discussion of results
Dimensional and visual inspection	Direct measurement of the mass, lengths, width, thickness with micrometers, calipers, pH meter or balance; and visual inspection.	Dimensional analysis was completed to verify the dimensions and visual characteristics and met specifications;
Pliability/ Tissue conformance and adherence	The device is placed on a simulated model and graded for visual conformance and adherence.	Visual inspection was conducted and met specifications.
Swelling	Direct measurement of the device (with micrometers, calipers) when exposed to fluid.	Dimensional analysis was completed and met specifications.
Strength/Puncture	Direct measurement of the device strength/puncture when measured with a probe.	Testing was completed and met specifications.
Pouch Seal Integrity/Sterile Barrier	The integrity of the pouch was verified with a visual inspection, peel tester, and burst tester.	Testing was completed and met specifications.
Sterilization	The e-beam sterilization process was validated to achieve a sterility assurance level (SAL) of 10^{-6} per ISO 11137	Testing was completed and met specifications.
Bacterial endotoxin validation	The bacterial endotoxin validation testing was conducted per USP <85> Bacterial Endotoxins and Ph.Eur. Chpt 2.6.14	Testing was completed and met specification
Cytotoxicity	The device was evaluated for potential cytotoxic effects using an in vitro mammalian cell culture test. This study was conducted following the guidelines of ISO 10993-5	The test extract showed no evidence of causing cell lysis or toxicity.
Sensitization	The device was evaluated for the potential to cause delayed dermal contact sensitization in a guinea pig maximization test. This study was conducted based on the requirements of ISO 10993-10	The test article showed no evidence of causing delayed contact sensitization.
Irritation	The device was evaluated for the potential to cause irritation following intracutaneous injection. This study was conducted based on ISO 10993-10	There was no evidence of significant irritation from the extracts injected intracutaneously.
Acute systemic toxicity	The device was evaluated for acute systemic toxicity. This study was conducted based on ISO 10993-11.	The sesame oil test article extracts and the sodium chloride test article extracts injected met the passing requirements of the test.
Pyrogenicity	The device was evaluated for material mediated pyrogenicity in the rabbit. The test was conducted	The total rise of temperatures during the observation period was

	based on USP, General Chapter <151>, Pyrogen Test. The procedure is recommended in ISO 10993-11	within acceptable USP limits.
Genotoxicity	The device was evaluated for mutagenic potential, mutagenic changes, and to produce cytogenetic damage	Extract did not cause cytogenetic damage/ micronuclei formation. Extracts were well within the limits defined for a negative response and the test article is considered non-mutagenic and considered to be non-mutagenic
Subchronic toxicity	The device was surgically implanted in the subcutaneous tissue of the rat to evaluate potential systemic toxicity and local tissue response at the implantation sites	No evidence of systemic toxicity following subcutaneous implantation. Microscopically, the test article was classified as a non-irritant.
Muscle implantation	The purpose of this study was to assess the local tissue effects and absorption profile following implantation in muscle tissue in at multiple timepoints.	At long term timepoints the device was considered to be a non-irritant and a slight irritant at earlier weeks following implantation when compared to the control. At the study mid-point, microscopic evaluation demonstrated the device is bioresorbing as expected. This variable and slight irritation is expected for a device undergoing absorption.
Neurotoxicity assessment	A risk analysis was conducted	An analysis was conducted to determine any neurotoxicity risk to the patient.

	Animal Study	The animal study was conducted on multiple injury types for subject device, predicate control device, and untreated groups. Nerve defects were comparable to the clinical use of the device. Data was collected at an early period, a mid-term period; and a late period. The rat is often used in nerve injury models and is suggested in the ISO standards and Organisation for Economic Co-operation and Development guidelines as an acceptable animal model for evaluating the local tissue response of various articles; and the sample size was selected to be large enough to show consistent results and to be able to compare the test, control, and untreated groups. As recommended by FDA, motor and sensory neurological assessments were conducted prior to surgery, and throughout the study. VersaWrap animals and the predicate control animals demonstrated equivalent safety and equivalent performance results; there were no significant events reported in any group. Histopathological evaluations were performed to assess local and systemic tissue effects specific to the test and predicate control articles. Overall, there was no apparent difference in the character or severity of the reactivity to the test or predicate implant. There were no microscopic changes in the nerve at any interval for either test or Integra implants; the microscopic appearance of the nerve and surrounding tissue for both the control and VersaWrap were similar.	

Conclusion	Based on the results of animal studies, prior in vitro product characterization studies, in vitro and in vivo biocompatibility and performance studies, we conclude the device is as safe as, and substantially equivalent to its predicate devices.