October 29, 2021

Alafair Biosciences Inc.
Angela Mallery
Principal Product Development Strategist, Regulatory
6101 W Courtyard Drive Suite 2-225
Austin, Texas 78730

Re: K213163
Trade/Device Name: VersaWrap
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTM
Dated: September 27, 2021
Received: September 28, 2021

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 and Part 809); 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,

Deborah Fellhauer RN, BSN
Assistant Director (Acting)
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K213163

Device Name
VersaWrap

Indications for Use *(Describe)*
VersaWrap is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue. The device may also be used in the management and protection of surrounding tissues such as skeletal muscle and ligament.

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.

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510(k) Summary VersaWrap® Tendon Protector	
Submitted by:	Alafair Biosciences, Inc. 6101 W Courtyard Drive Ste. 2-225 Austin, TX 78730 800.206.5586; info@alafairbiosciences.com
Date Prepared:	October 29, 2021
Contact:	Ben Walthall, Ph.D. Chief Regulatory Officer 800.206.5586; info@alafairbiosciences.com
Product Name	VersaWrap
Common Name	Tendon Protector
Classification number	21 CFR 878.3300
Product Code	FTM
Predicate Device:	K203600 VersaWrap
Device Description:	VersaWrap® is an absorbable implant (device), designed to serve as an interface between the target tissues and surrounding tissues to provide a non-constricting, protective encasement. VersaWrap consists of a clear Sheet and a wetting Solution. The clear Sheet is a thin membrane of crosslinked calcium alginate and glycosaminoglycan (GAG). VersaWrap Sheet is easy to handle, conformable, and is designed for placement under, around, or over injured tissues and/or surrounding tissues. VersaWrap Sheet is supplied sterile, non-pyrogenic, for single use, in double peel pouches. The VersaWrap Solution is applied to the Sheet rendering the Sheet a gelatinous, tissue adherent layer. The Solution, comprised of aqueous citrate, is provided sterile, non-pyrogenic, for single use, in a dropper, packaged in a double peel pouch.
Indications for Use:	VersaWrap is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue. The device may also be used in the management and protection of surrounding tissues such as skeletal muscle and ligament.
Comparative Technology Characteristics:	VersaWrap can be implanted in gel form as compared to the predicate
Non-Clinical Tests Performed:	Non-Clinical testing was conducted and results were substantially equivalent the prior non-clinical testing
Conclusion	Conclusion(s) drawn from the nonclinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the identified legally marketed device