June 14, 2024

Alafair Biosciences Inc.
Dr. Sarah Mayes
Official Correspondent
6101 W Courtyard Dr Ste 1-225
Austin, Texas 78730

Re: K240817
Trade/Device Name: VersaWrap®
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWW
Dated: April 23, 2024
Received: April 24, 2024

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.

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,

Robert M. Stefani -S

Digitally signed by Robert M. Stefani -S
Date: 2024.06.14 17:19:00 -04'00'

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.

Submission Number *(if known)*

K240817

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 ligaments.
In these procedures, VersaWrap may encounter a variety of implanted structures such as anchors, grafts, staples, and sutures.

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.

510(k) Summary

Prepared on: June 10, 2024

Contact Details

Submitted by: Alafair Biosciences, Inc.
6101 W Courtyard Drive Ste. 1-225
Austin, TX 78730

Contact: Dr. Sarah Mayes
Alafair Biosciences Inc.
6101 W Courtyard Dr Ste 1-225
Austin TX 78730 United States
Phone: 512-739-9510
Email: info@alafairbiosciences.com

Device Name

Product Name	VersaWrap®
Common Name	Surgical Mesh
Classification number	21 CFR 878.3300
Classification name	Mesh, Surgical, Absorbable, Orthopaedics, Reinforcement of Tendon
Product Code	OWW

Legally Marketed Predicate Device

VersaWrap® (K213163)

Device Description Summary

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 hydrogel (Sheet) and a wetting Solution. The clear Sheet is a thin membrane of alginate and hyaluronic acid. VersaWrap Sheet is easy to handle, conformable, and is designed for placement under, around, or over injured tissues and/or surrounding tissues. In these procedures, VersaWrap may encounter a variety of implanted structures such as anchors, grafts, staples, and sutures. VersaWrap Sheet is supplied sterile, non-pyrogenic, for single use, in double peel pouches. The VersaWrap Solution is applied to the Sheet to render the Sheet a gelatinous, tissue adherent layer (gel). The Solution, comprised of aqueous citrate, is provided sterile, non-pyrogenic, for single use, in a dropper, packaged in a double peel pouch.

Intended Use/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 ligaments. In these procedures, VersaWrap may encounter a variety of implanted structures such as anchors, grafts, staples, and sutures.

Indications for Use Comparison

The additional description in the labeling is further identifying the surrounding environment and 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 device is not being used differently. The risk-based assessment did not identify any new risks or significantly modified existing risks.

Therefore, the subject device can be considered to be substantially equivalent to the predicate device

Technology Comparison

The subject device has the identical technological characteristics as the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

Based on the risk-based assessment no additional non-clinical testing is required to support the additional determination of substantial equivalence. The prior non-clinical and animal testing for the device were used to support the extended indications.

Based on the risk-based assessment no clinical testing is required to support the additional determination of substantial equivalence.

The subject device can be considered to be substantially equivalent to the predicate device.