July 18, 2025

Alafair Biosciences
Sarah Mayes
Chief Scientific Officer
6101 W Courtyard Dr
Ste 1-225
Austin, Texas 78730

Re: K251655
Trade/Device Name: VersaCoat Tendon Protector (VTP-44G2); VersaCoat Tendon Protector (VTP-12G1)
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWW
Dated: May 30, 2025
Received: May 30, 2025

Dear Sarah 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,

CHRISTOPHER FERREIRA -S

Christopher Ferriera, M.S.
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

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.	K251655

Please provide the device trade name(s).

VersaCoat Tendon Protector (VTP-44G2);
VersaCoat Tendon Protector (VTP-12G1)

Please provide your Indications for Use below.

VersaCoat Tendon Protector 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 to manage and protect surrounding tissues such as ligament and skeletal muscle. In these procedures, the device may encounter implanted structures such as anchors, grafts, staples, or sutures.

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

K#251655

Prepared on: July 14, 2025

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	VersaCoat Tendon Protector
Common Name	Surgical Mesh
Classification number	21 CFR 878.3300
Product Code	OWW
Legally Marketed Predicate Device	
VersaWrap Tendon Protector (K240817)	
Device Description Summary	
VersaCoat Tendon Protector is an absorbable implant (device) designed to function as a gelatinous interface between an injured tendon and surrounding tissues, providing a non-constricting, protective encasement for injured tendons. VersaCoat Tendon Protector consists of a Hydrogel Pellet and Wetting Solution. The Pellet is a hollow, cylindrical hydrogel of alginate and hyaluronic acid. The Pellet is easy to handle and is designed for quick hydration with the Wetting Solution. The Pellet is supplied sterile, non-pyrogenic, for single use, in double peel pouches. The Wetting Solution hydrates the Pellet, rendering a viscous, flowable, tissue-adherent gel. The Wetting Solution is aqueous citrate and is provided in a dropper packaged in a double peel pouch. The Wetting Solution is sterile, non-pyrogenic, and is intended for single use only. A sterile container (dual syringe system) is offered and may be used to facilitate hydration of the Pellet with Wetting Solution.	
Intended Use/Indications for Use	
VersaCoat Tendon Protector 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 to manage and protect surrounding tissues such as ligament and skeletal muscle. In these procedures, the device may encounter implanted structures such as anchors, grafts, staples, or sutures.	
Principle of Operation	
The mechanism of action of VersaCoat Tendon Protector is to manage tendon injuries, and surrounding tissue such as ligament and skeletal muscle, by providing a gliding surface and by keeping damaged tissues physically separated during healing	
Functional and Safety Testing	
To verify that device design met functional and performance requirements, representative samples of the device underwent bench testing in accordance to applicable standards and guidance. These data provide an acceptable assurance of the safety and effectiveness of VersaCoat Tendon Protector and demonstrate that the device is equivalent to the predicate. Biocompatibility studies have demonstrated that VersaCoat Tendon Protector is non-	

cytotoxic, non-pyrogenic, non-irritating, non-sensitizing, non-toxic, and non-genotoxic. Results of bench testing studies have demonstrated that the VersaCoat Tendon Protector alginate-hyaluronic acid flowable matrix provides a protective interface to protect injured tendon. Endotoxin testing is performed for each production Lot per an established sampling plan.

Non-Clinical and/or Clinical Tests Summary & Conclusions

The following tests were performed to support substantial equivalence.
Performance Testing, including:

- Visual inspection
- Dimensional and weight measurements
- Gel integrity
- Handling
- Tissue adherence and conformance

Biocompatibility Testing, including:

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Irritation - Intracutaneous Reactivity (ISO10993-10)
- Acute Systemic Toxicity (ISO10993-11)
- Pyrogenicity (ISO 10993-11)
- Genotoxicity (ISO 10993-3)
- Subchronic toxicity (13 weeks, ISO 10993-11 and ISO 10993-6)
- Muscle implantation toxicity/irritation (ISO 10993-6)

Comparative Technology Characteristics

A comparison of the subject device and the predicate device demonstrates equivalent technological characteristics. Equivalence is based upon intended use, indications for use, materials of construction, operating principle, fundamental scientific technology, and performance. When implanted, the subject and predicate device are identical. Minor technological characteristic differences do not raise new questions of safety and effectiveness.

Conclusion

No new questions of safety or effectiveness were identified during device testing; therefore, the VersaCoat Tendon Protector device is considered substantially equivalent to the predicate device(s) in terms of safety and effectiveness.