DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 10, 2016

Alafair Biosciences Inc.
Ben Walthall, Ph.D.
Chief Regulatory Officer
3925 W. Braker Lane, Floor #3
Austin, Texas 78759

Re: K160364
Trade/Device Name: Versawrap Tendon Protector
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWW
Dated: May 9, 2016
Received: May 11, 2016

Dear Dr. Walthall:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160364

Device Name
VersaWrap Tendon Protector

Indications for Use *(Describe)*
The VersaWrap Tendon Protector is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon 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.

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 Incorporated
3925 West Braker Lane, Third Floor
Austin, Texas 78759
Telephone: 512-430-4967

Contact: Ben Walthall, Ph.D.
Chief Regulatory Officer

Date prepared: May 9, 2016

Name of the device: Proprietary Name: VersaWrap™ Tendon Protector
Common Name: Tendon Protector
Class II
Regulation Number: 21 CFR 878.3300
Product Code: OWW
Review Panel: General & Plastic Surgery

Predicate Device: VersaWrap™ Tendon Protector (VersaWrap) is substantially equivalent in construction, function and intended use to Integra Lifesciences Corporation's Tendon Wrap™ Tendon Protector (Tendon Wrap), K053655.

Device Description: VersaWrap is an absorbable implant (device), designed to serve as an interface between the tendon and tendon sheath or the surrounding tissues, which provides a non-constricting, protective encasement for injured tendons. VersaWrap consists of a Sheet and a wetting Solution. The Sheet is a thin membrane of crosslinked calcium alginate and glycosaminoglycan. VersaWrap Sheet is easy to handle, conformable, and is designed for easy placement under, around, or over the injured tendon. VersaWrap Sheet is supplied sterile, non-pyrogenic, for single use, in double peel pouches. The VersaWrap Solution is applied to the Sheet after the Sheet is positioned onto damaged tissue. The Solution is comprised of aqueous citrate and is provided in a dropper packaged in a double peel pouch. The Solution is sterile, non-pyrogenic, and is intended for single use only.

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.

Principle of Operation:

The mechanism of action of VersaWrap is to protect tendon 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 VersaWrap and demonstrate that the device is equivalent to the predicate.

Biocompatibility studies have demonstrated that VersaWrap is non-cytotoxic, non-pyrogenic, non-irritating, non-sensitizing, non-toxic, and non-genotoxic. Results of physical testing and animal studies have demonstrated that the VersaWrap alginate-glycosaminoglycan matrix provides a protective interface to improve mobility of repaired tendons.

Comparative Technology Characteristics:

A comparison of the characteristics of the proposed device and the predicate device shows VersaWrap to have the same technological characteristics to the predicate that has received 510(k) clearance.

Equivalence is based upon intended use, indications for use, operating principle and fundamental scientific technology.

Both devices are intended for the management and protection of tendon injuries. Minor differences in technological characteristics do not raise different questions of safety and effectiveness.

Non-Clinical Tests Submitted

The following tests were performed to support substantial equivalence.

- Performance Testing, including:
  - Visual inspection
  - Dimensional and weight measurements
  - Puncture strength
  - Handling
  - Tissue adherence and conformance
  - Chicken flexor tendon repair model
- 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)

Conclusion: Alafair considers VersaWrap to be equivalent to the predicate device. This conclusion is based upon the fact that the devices have an equivalent intended use, and there are no differences that raise new types of questions of safety and effectiveness.