



June 6, 2025

TYBR Health
% Scott Bruder
Founder and CEO
Bruder Consulting & Venture Group
38 True Harbour Way
West Islip, New York 11795

Re: K250109

Trade/Device Name: TYBR Collagen Gel
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWY, FTM
Dated: April 15, 2025
Received: April 16, 2025

Dear Scott Bruder:

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 Ferreira, MS
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

Submission Number (if known)

K250109

Device Name

TYBR Collagen Gel

Indications for Use (Describe)

TYBR Collagen Gel 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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K250109

510(k) Summary

Submitter

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Correspondent

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Date Prepared

June 6, 2025

Device

Trade Name	TYBR Collagen Gel
Common Name	Mesh, surgical, collagen
Regulation	21 CFR 878.3300 Surgical Mesh
Classification	Class II
Product Code	OWY (Primary), FTM
Panel	Orthopedic

Predicates

Primary Predicate	Alafair Biosciences - VersaWrap (K213163)
Additional Predicate	MiroMatrix – Miromatrix Biological Mesh (K162570)

Device Description

TYBR Collagen Gel is a naturally-derived collagenous semi-permeable barrier device that conforms to the application site and degrades within 30 days. The TYBR Collagen Gel includes a blue color additive to aid with visualization. The applicator provides controlled delivery of the collagen gel to support uniform coverage at the desired location.

Indications for Use Statement

TYBR Collagen Gel 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.



Substantial Equivalence

This submission demonstrates that TYBR Collagen Gel is substantially equivalent to Alafair Biosciences' VersaWrap (K213163) and MiroMatrix – Miromatrix Biological Mesh (K162570). All are orthopedic meshes indicated for use in tendon repair. Both TYBR Collagen Gel and VersaWrap are also indicated for management and protection of surrounding tissue such as skeletal tissue and ligament.

TYBR Collagen Gel is composed of collagen, whereas the primary predicate device, VersaWrap, is composed from cross-linked calcium alginate and glycosaminoglycan (GAG). However, both products are resorbable and both form gels when applied to the implantation site. Additionally, TYBR Collagen Gel shares similarities to the secondary predicate, which is also made from collagen. TYBR Collagen Gel also includes a color additive. Both TYBR Collagen Gel and VersaWrap Primary predicate require user preparation. However, TYBR Collagen Gel includes an applicator to facilitate implantation versus the Primary Predicate, which must be applied by hand. These differences do not raise any difference questions of safety and effectiveness, and the testing supports that TYBR Collagen Gel is as safe and as effective as VersaWrap Primary Predicate for the stated indications for use.

Performance

To support that the subject device is as safe and as effective as the predicate, TYBR Health provides device characterization, sterilization, shelf-life, endotoxin, viral inactivation, cadaveric simulated use testing, and biocompatibility test data to support substantial equivalence. The biomechanical effects of the gel and the risk of improper gel application was addressed in a cadaver finger model that assessed loading necessary for tendon sliding and gliding compared to untreated digits. The biomechanical cadaver testing demonstrated that there was no negative impact from under- and over-application of TYBR gel. Additionally, TYBR Health provided animal performance studies in a chicken flexor tendon repair model that assessed TYBR gel performance compared to the VeraWrap predicate at three timepoints. The animal studies evaluated tendon rupture strength, histopathology, gross pathology (e.g., adhesion scoring), and range of motion and demonstrated the performance of the subject device is substantially equivalent.

Summary

The subject device and predicates have the same intended use, and the same specific indications for use. Any differences in technological characteristics between the subject device and predicate do not raise different questions of safety and effectiveness and have been addressed with performance testing. TYBR Health concludes that the device is substantially equivalent to the predicates.