



September 28, 2026

TELA Bio, Inc.
John Urtz
Director - Regulatory and Quality
1 Great Valley Pkwy.
Suite 24
Malvern, Pennsylvania 19355

Re: K260474
Trade/Device Name: Liora Monofilament Scaffold
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: August 26, 2026
Received: August 26, 2026

Dear John Urtz:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

TEK N.
LAMICHHANE-S

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive Surgery Devices
OHT4: Office of Surgical and
Infection Control 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.

K260474

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Please provide the device trade name(s).

?

Liora Monofilament Scaffold

Please provide your Indications for Use below.

?

Liora is indicated for soft tissue reinforcement where weakness exists. It is indicated specifically in muscle flap transfer procedures as a temporary support to assist in securing muscle flaps to defect sites.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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510(k) Summary (K260474)

Device trade name:	Liora Monofilament Scaffold
Device common name:	Surgical Mesh
Classification name:	Mesh, surgical, polymeric
Regulation number:	21 CFR § 878.3300
Product code:	FTL
Submitter:	TELA Bio, Inc. 1 Great Valley Parkway Suite 24 Malvern, PA 19355
Contact person:	John Urtz Director – Regulatory and Quality TELA Bio, Inc. jurtz@telabio.com ; 484-320-2884
Date prepared:	September 23, 2026

Predicate device:	Polydioxanone Surgical Scaffold
510(k) number:	K181094
Regulation number:	21 CFR § 878.3300
Product code:	FTL
Purpose of predicate device:	Primary predicate device utilized for comparison of intended use and technological characteristics including head-to-head preclinical and <i>in vitro</i> testing.

Reference device:	OviTex PRS (Long-Term Resorbable)
510(k) number:	K243595
Regulation number:	21 CFR § 878.3300
Product code:	FTM , FTL
Purpose of reference device:	Reference device utilized for comparison of preclinical bench testing results.

Reference device:	TIGR Matrix
510(k) number:	K191749
Regulation number:	21CFR878.3300
Product code:	FTL, OWT, OOD
Purpose of reference device:	Reference device utilized for purposes of head-to-head <i>in vivo</i> implantation testing.

Device Description

Liora Monofilament Scaffold ("Liora") is a sterile resorbable monofilament scaffold composed of 100% Poly(lactic co-glycolic acid) ("PLGA"). Liora is provided in various shapes and sizes to suit surgeon preference and the nature of the soft tissue repair. The device may be trimmed to further accommodate an individual patient's requirements.

Intended Use / Indications for Use

Liora is indicated for soft tissue reinforcement where weakness exists. It is indicated specifically in muscle flap transfer procedures as a temporary support to assist in securing muscle flaps to defect sites.

Indications for Use Comparison

Liora has the same intended use as the predicate device, Polydioxanone Surgical Scaffold as both devices are indicated for soft tissue reinforcement where weakness exists. Liora is further specified for use in muscle flap procedures as a temporary support to assist in securing muscle flaps to defect sites.

Summary Comparing the Technological Characteristics of the Subject and Predicate / Reference Devices

Liora has similar technological characteristics as the predicate device as both are 100% resorbable surgical meshes made from monofilament materials. Differences between the subject and predicate devices include materials of construction and physical properties such as thickness, areal density, and pore size. Liora is offered in shapes and sizes similar to the predicate device and reference devices.

Although differences exist between Liora and the predicate and reference devices, these differences do not raise different questions of safety or effectiveness. Any measured differences between the subject and predicate device are not clinically significant with respect to Liora's indications for use and are supported by preclinical bench testing performed on both Liora and the reference device(s).

A comparison of the technological characteristics is included in the table below.

510(k) Summary – Liora Monofilament Scaffold-K260474

	<u>Subject Device</u> Liora Monofilament Scaffold	<u>Predicate Device</u> Polydioxanone Surgical Scaffold (K181094)	<u>Reference Device</u> OviTex PRS LTR (K243595)	<u>Reference Device</u> TIGR Matrix (K191749)	Comparison (Subject to Predicate)
Indications for Use	Liora is indicated for soft tissue reinforcement where weakness exists. It is indicated specifically in muscle flap transfer procedures as a temporary support to assist in securing muscle flaps to defect sites.	Polydioxanone Surgical Scaffold is intended for use in reinforcement of soft tissue where weakness exists.	OviTex PRS is for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery. The device is supplied sterile and is intended for one-time use.	The TIGR Matrix Surgical Mesh is indicated for use in the reinforcement of soft tissue, where weakness exists in patients undergoing plastic and reconstructive surgery, or for use in procedures involving soft tissue repair, such as for the repair of hernias or other fascial defects that require the addition of a reinforcing material to obtain the desired surgical result.	Equivalent
Regulation Number	21 CFR § 878.3300	21 CFR § 878.3300	21 CFR § 878.3300	21 CFR § 878.3300	Identical
Product Code	FTL	FTL	FTM, FTL	FTL, OWT, OOD	Identical
Materials of Construction	Poly (lactic-co-glycolic Acid) ("PLGA") – 100% resorbable polymer	Polydioxanone ("PDO") – 100% resorbable polymer	Ovine derived collagen and Poly (lactic-co-glycolic Acid) (PLGA) resorbable polymer	Copolymer of glycolide / lactide / trimethyl carbonate (40% w/w) and copolymer of lactide / trimethyl carbonate (60% w/w) – 100% resorbable polymer	Equivalent
Degradation Method	Bulk hydrolysis	Bulk hydrolysis	Enzymatic and bulk hydrolysis	Bulk hydrolysis	Identical

510(k) Summary – Liora Monofilament Scaffold-K260474

	<u>Subject Device</u> Liora Monofilament Scaffold	<u>Predicate Device</u> Polydioxanone Surgical Scaffold (K181094)	<u>Reference Device</u> OviTex PRS LTR (K243595)	<u>Reference Device</u> TIGR Matrix (K191749)	Comparison (Subject to Predicate)
Device Thickness (range)	0.498mm – 0.537mm	0.427mm – 0.431mm	0.596mm – 0.878mm	0.687mm – 0.713mm	Equivalent
Areal Density (range)	43.0 – 54.0 g/m ²	74.2 – 76.0 g/m ²	N/A	147.8 – 152.3 g/m ²	Equivalent
Mean Major Pore Size (Linear)	2.8mm x 2.5mm	2.0mm x 1.6mm	N/A	1.0mm x 2.3mm	Equivalent
Mean Major Pore Size (Areal)	4.84mm ²	1.83mm ²	N/A	1.71mm ²	Equivalent
Shapes Offered	Rectangle, Contour, Circle	Rectangle	Rectangle, Contour, Circle, Oval	Rectangle	Equivalent
Maximum Surface Area (footprint)	750cm ²	500cm ²	641cm ²	600cm ²	Equivalent
Usage	Single use	Single use	Single use	Single use	Identical
Biocompatibility¹	Established	Established	Established	Established	Identical
Sterilization method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Identical
Sterility Assurance Level (SAL)	10 ⁻⁶	10 ⁻⁶	10 ⁻⁶	10 ⁻⁶	Identical

¹ In accordance with ISO 10993-1:2018 – Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process

Non-clinical Performance Data

Nonclinical testing was conducted based on the FDA Guidance, Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh. The data submitted in this application includes preclinical and animal studies on biocompatibility, benchtop performance, packaging, sterilization, and shelf-life.

Biocompatibility evaluation was conducted per ISO 10993-1 with cytotoxicity, sensitization, irritation, acute systemic toxicity, genotoxicity, implantation, hemolysis, and material mediated pyrogenicity testing completed. Comprehensive chemical characterization was conducted per ISO 10993-18 and a toxicological risk assessment completed to address additional biocompatibility endpoints. The overall biological evaluation report assessed all completed testing and found that the device is biocompatible.

Benchtop testing included device characterization (thickness, areal density, and pore size), tensile strength per ASTM D638-22, device stiffness per ASTM D1388-23, suture pullout strength, burst strength per ASTM D6797-24, and tear resistance per ISO 9073-4:2021. Predicate and reference devices were tested head-to-head against the subject device. Simulated use testing was also conducted on the subject device. *In vivo* implantation data were also used to support the performance of the device.

Benchtop mechanical and *in vitro* testing per ASTM F1635-24 Standard Test Method for *in vitro* Degradation Testing of Hydrolytically Degradable Polymer Resins and Fabricated Forms for Surgical Implants has been conducted and shows that Polydioxanone Surgical Scaffold retains greater strength than Liora at the time of implantation through approximately two months. Throughout that timeframe, Liora has mechanical strength equivalent to the implantation strength of the reference device, OviTex PRS (Long-Term Resorbable). Liora retains its original strength for approximately three months based on *in vitro* degradation testing.

Clinical Performance Data

Substantial equivalence was not based on an assessment of clinical performance data.

Conclusion

All evaluations, including biocompatibility testing, animal testing, mechanical testing, and *in vitro* degradation testing support that the Liora device is substantially equivalent to the predicate device, Polydioxanone Surgical Scaffold (K181094).