December 19, 2024

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

Re: K243595
Trade/Device Name: OviTex PRS (Long-Term Resorbable)
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTM, FTL
Dated: November 20, 2024
Received: November 20, 2024

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.

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,

Irada S. Isayeva -S

Digitally signed by Irada S. Isayeva -S
Date: 2024.12.19 17:39:25 -05'00'

for 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

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)*

K243595

Device Name

OviTex PRS (Long-Term Resorbable)

Indications for Use *(Describe)*

OviTex PRS (Long-Term Resorbable) 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) #:

510(k) Summary

Prepared on: 2024-12-10

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	TELA Bio, Inc.
Applicant Address	1 Great Valley Parkway Suite 24 Malvern PA 19355 United States
Applicant Contact Telephone	4843202884
Applicant Contact	Mr. John Urtz
Applicant Contact Email	jurtz@telabio.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	OviTex PRS (Long-Term Resorbable)
Common Name	Surgical mesh
Classification Name	Mesh, Surgical
Regulation Number	878.3300
Product Code(s)	FTM, FTL

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K214070	OviTex PRS (Long-Term Resorbable)	FTM

Device Description Summary

21 CFR 807.92(a)(4)

OviTex PRS Long-Term Resorbable (OviTex PRS LTR) is a sterile reinforced tissue matrix composed of biological tissue (ovine extracellular matrix) and Poly(lactic co-glycolic acid). The device contains bidirectional fenestrations to allow for multidirectional stetch. The polymer imparts additional structure to the ECM and maintains device integrity through the initial phases of healing. OviTex PRS is provided in various shapes and sizes to suit surgeon preference and nature of the soft tissue repair in plastic and reconstructive surgery. The device may be trimmed to a desired shape to further accommodate an individual patient's requirements.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

OviTex PRS (Long-Term Resorbable) 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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are the same for the subject device as the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device has the same technological characteristics as the predicate device including materials of construction and principle of operation. There are two changes between the subject and the predicate device.

First, all OviTex PRS Long-Term Resorbable devices have been modified to remove a layer of foil packaging. The sterile barrier is

unchanged.

Second, two additional device configurations are being introduced - a 25cm diameter circle and a 25x30cm oval. Both devices contain three layers of decellularized extracellular matrix and are embroidered together with Poly(lactic co-glycolic Acid) suture.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Real-time shelf life testing was utilized to confirm that OviTex PRS LTR meets specification through 18 months of storage.

The additional device offerings underwent non-clinical testing including endotoxin and ethylene oxide sterilization residuals (ISO 10993-7:2008) quantification. The results of testing showed that these devices met the predefined acceptance criteria.

Overall, the results of non-clinical testing support a determination of substantial equivalence between the subject devices and the predicate device.