



May 22, 2024

Tela Bio, Inc.
John Urtz
Associate Director, RA/QA
1 Great Valley Parkway Suite 24
Malvern, Pennsylvania 19355

Re: K241126
Trade/Device Name: OviTex PRS
Regulation Number: CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM, FTL
Dated: April 23, 2024
Received: April 23, 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.

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

Digitally signed by
Tek N. Lamichhane -S
Date: 2024.05.22
16:12:50 -04'00'

Tek N. Lamichhane, Ph.D.

Assistant Director

DHT4B: Division of Infection Control

and 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

Submission Number (if known)

K241126

Device Name

OviTex PRS

Indications for Use (Describe)

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.

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.

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510(k) Summary

Prepared on: 2024-05-22

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	484-320-2884
Applicant Contact	Mr. John Urtz
Applicant Contact Email	jurtz@telabio.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	OviTex PRS
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
K183398	Endoform Restella	FTM

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

OviTex PRS is a sterile reinforced tissue matrix composed of biological tissue (ovine extracellular matrix) and Polyglycolic Acid (PGA) or Polypropylene (PP), known as OviTex PRS (STR) (or OviTex PRS Short Term Resorbable) and OviTex PRS PP (or OviTex PRS Permanent), respectively. The device contains unidirectional fenestrations to allow for stretching in a uniaxial direction. 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 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 three changes noted between the subject device and the predicate device.

First, the device name has changed from Endoform Restella to OviTex PRS. All labeling has been updated accordingly and no new or changed risks are introduced by this change.

Second, the shelf life of OviTex PRS (PP) has been updated from 24 to 36 months utilizing the same methods as utilized in the original K183398 submission.

Finally, the predicate device was cleared in various sizes (i.e. surface areas) and shapes utilizing three layers of ovine forestomach matrix (OFM). The subject device has been modified to include additional OviTex PRS (STR) device offerings with two layers of OFM. Proposed sizes/surface areas and shapes are within the previously cleared range. There are no additions or device changes to the OviTex PRS Permanent line.

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

Non-clinical testing was conducted on the additional device offerings showing that the two layer OviTex PRS (STR) devices meet all specifications originally submitted. This testing included mechanical testing (tensile strength, compliance, and suture retention). Further, performance testing (shelf-life testing) of relevant product attributes was conducted for both OviTex PRS (STR) and OviTex PRS Permanent to establish a 12 month shelf life for the additional two layer OviTex PRS (STR) device offerings and to validate the OviTex PRS Permanent shelf life extension from 24 to 36 months. Packaging stability tests supporting shelf life for OviTex PRS Permanent (36 months) and OviTex PRS (STR) (12 months) include dye penetration, seal strength testing, and visual inspection.

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