March 21, 2023

TELA Bio
John Urtz
Senior Manager, Regulatory and Quality
1 Great Valley Parkway, Suite 24
Malvern, Pennsylvania 19355

Re: K214070
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, FTM, FTL
Dated: December 23, 2021
Received: December 27, 2021

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 (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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Deborah A. Fellhauer -S

Deborah Fellhauer RN, BSN
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
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and Infection Control Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K214070

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.

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510(K) SUMMARY

Device trade name:	OviTex PRS (Long-Term Resorbable)
Device common name:	Mesh, surgical
Regulation number:	§878.3300, Surgical Mesh
Product code(s):	FTM / FTL
Predicate device:	Endoform Restella (K183398)
Reference device:	Endoform Reconstructive Template (Non-Absorbable) (K181935)
Owner / Submitter:	TELA Bio, Inc. 1 Great Valley Parkway Suite 24 Malvern, PA 19355
Contact Person:	John Urtz Sr. Manager, Quality and Regulatory TELA Bio, Inc. jurtz@telabio.com 484-320-2884
Date prepared:	16 March 2023

Device Description

OviTex PRS (Long-Term Resorbable) is a surgical mesh manufactured by layering sheets of ovine forestomach matrix to create multi-layer configurations of devices sewn together with resorbable Poly(lactic-co-glycolic Acid) ("PLGA") suture for use in plastic and reconstructive surgery. The 2-8 ply devices are available in surface areas up to 434 cm^2 in various shapes.

Intended Use / Indications for Use

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.

Summary/Comparison of Technological Characteristics

OviTex PRS (Long-Term Resorbable) has the same indications for use as the predicate device, Endoform Restella. The principle of operation is also the same.

The subject device, OviTex PRS (Long-Term Resorbable) has similar technological characteristics as the predicate device. Both devices are composed of sheets of ovine forestomach matrix and are sewn together with a polymeric suture. The main differences between the subject and predicate device are the polymeric suture material (PLGA in the subject device vs. Polyglycolic Acid ("PGA") or Polypropylene ("PP") in the predicate device) and the directionality of the ovine tissue fenestrations (bi-directional for the subject device and uni-directional for the predicate device). The subject device is offered in a broader range of shapes, sizes, and thicknesses compared to the predicate, but within the range of

sizes/thicknesses of the reference device. OviTex PRS (Long-Term Resorbable) maintains the same fundamental technological characteristics as the predicate device with respect to material types, biocompatibility, device specifications, and sterilization.

Characteristic	**Subject Device** OviTex PRS (LTR)	**Predicate Device** Endoform Restella	**Reference Device** Endoform Reconstructive Template (Non-absorbable)
510(k) Number	K214070	K183398	K181935
Product Code	FTM / FTL	FTM / FTL	FTL / FTM
Regulation Number	§878.3300, Surgical Mesh	§878.3300, Surgical Mesh	§878.3300, Surgical Mesh
Common Name	Mesh, surgical	Mesh, surgical	Mesh, surgical
Indications for Use	OviTex PRS (Long-Term Resorbable) is intended for use in the reinforcement of 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.	Endoform Restella is intended for use in the reinforcement of 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.	Endoform Reconstructive Template - Non-Absorbable is intended for use as a surgical mesh to reinforce and/or repair soft tissue where weakness exists. Indications for use include the repair of hernias and/or abdominal wall defects that require the use of reinforcing or bridging material to obtain the desired surgical outcome.
Animal Derived Tissue	Ovine forestomach matrix	Ovine forestomach matrix	Ovine forestomach matrix
Polymeric Suture	Poly(lactic-co-glycolic Acid)	Polyglycolic Acid OR Polypropylene	Polypropylene
Layering Configurations	2-8 layers	3 layers	1-10 layers
Maximum Device Size	434cm^2	399cm^2	1000cm^2
Shapes Offered	Rectangle, Contour, Oval	Rectangle, Contour	Rectangle
Tissue Fenestrations	Bi-directional	Uni-directional	None
Biocompatibility	Established	Established	Established

Characteristic	**Subject Device** OviTex PRS (LTR)	**Predicate Device** Endoform Restella	**Reference Device** Endoform Reconstructive Template (Non-absorbable)
Endotoxin Content	< 20 EU/device	< 20 EU/device	< 20 EU/device
Sterilization Method and Sterility Assurance Level (SAL)	Ethylene Oxide, 10^{-6}	Ethylene Oxide, 10^{-6}	Ethylene Oxide, 10^{-6}
Usage	Single use only	Single use only	Single use only

Non-clinical Performance Data

Preclinical testing was conducted on OviTex PRS (Long-Term Resorbable) devices to demonstrate substantial equivalence to the predicate device. New bench testing included mechanical strength, suture retention, endotoxin, and compliance testing. Results of the testing confirms that the proposed device meets all product specifications.

Biocompatibility assessment and testing was performed in accordance with ISO 10993-1 on the final, finished device. Additionally, extractable and Leachable (E&L) testing was conducted on the final finished PLGA polymeric suture. A comprehensive assessment of each of the characterized chemicals obtained from this testing was incorporated into a toxicological risk assessment (TRA) regarding the final finished subject device in accordance with ISO 10993-18. The results of all performed biocompatibility testing and the accompanying toxicological risk assessment establish the biocompatibility of the OviTex PRS (LTR) device family.

An implantation study was conducted in accordance with ISO 10993-6 for a permanent implant contacting tissue which compared the local tissue response of the subject device to that of the predicate device. The results of this study showed that all devices had advanced to complete resorption by 78 weeks and that the subject device was substantially equivalent to the predicate device, classified as a non-irritant in terms of the local tissue response.

Clinical Performance Data

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

Conclusion

The results of preclinical, mechanical, and biocompatibility testing demonstrate that OviTex PRS (Long-Term Resorbable) is substantially equivalent to the predicate device.