June 18, 2019

Tisgenx
Kris Kupumbati
President
15615 Alton Parkway, Suite 450
Irvine, California 92618

Re: K182493
Trade/Device Name: Bovine Pericardial Tissue Patch
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTM
Dated: May 6, 2019
Received: May 21, 2019

Dear Mr. Kupumbati:

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,

For Nina Mezu-Nwaba, PharmD., MPH., MSc,
CAPT., United States Public Health Service
Assistant Director (Acting), Plastic Surgery Implant Devices Team
Division of Infection Control and Plastic Surgery Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182493

Device Name
Bovine Pericardial Tissue Patch

Indications for Use *(Describe)*
Tisgenx's Bovine Pericardial Tissue Patch is intended for use as a surgical patch for cardiac and vascular reconstruction and repair, soft tissue deficiency repair, and reinforcing the suture line during general surgical procedures.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5.0: 510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Information

Name	Tisgenx, Inc.
Address	15615 Alton Parkway, Suite 450 Irvine, CA 92618
Telephone	949-315-7157
Contact at Tisgenx Inc.	Kris Kupumbati
Contact Email Address	kris.kupumbati@tisgenx.com
Previous Correspondence	None

Device Information

Trade Name/ Product Name	Bovine Pericardial Tissue Patch
Common/ Usual Name	Surgical Mesh
Regulation Name	Mesh, Surgical
Review Panel	General & Plastic Surgery
Product Code(s)	FTM
Regulation Number	21 CFR 878.3300
Device Class	2

Predicate Device Information

Trade Name/ Product Name	Peripatch Sheet
Manufacturer	PM Devices, Inc.
Common Name	Surgical Mesh
Product Code(s)	FTM
Regulation Number	21 CFR 878.3300
Device Class	2
510(K) Number	K040835

This predicate device has not been subject to a recall.

5.1 Device Description

The Tisgenx Bovine Pericardial Tissue Patch is a bovine pericardium that is chemically crosslinked using a glutaraldehyde solution to impart stability. The device is provided terminally sterile, packaged in a sterile barrier jar filed with a liquid chemical sterilant. The device is intended for single patient use as a surgical patch for cardiac and vascular reconstruction and repair, soft tissue deficiency reconstruction and repair, and reinforcing the suture line during general surgical procedures.

5.2 Indications For Use

Tisgenx's Bovine Pericardial Tissue Patch is intended for use as a surgical patch for cardiac and vascular reconstruction and repair, soft tissue deficiency repair, and reinforcing the suture line during general surgical procedures.

5.3 Comparison of Technological Characteristics With The Predicate Device

The proposed device has the same or similar material composition and design features as the noted predicate as follows:

- Material Composition: Bovine pericardium; same as the predicate.
- Processing: Glutaraldehyde crosslinking; same as the predicate.
- Physical Form: Flat, square & rectangular patches; Same as the predicate.
- Implant Sizes: Patches of various length & width; similar to the predicate
- Packaging: Sealed sterile barrier container; Same as the predicate.
- Sterilization: Liquid chemical sterilization; Similar to the predicate.
- Mechanical Properties: Tensile strength, suture retention strength & % elongation are similar to the predicate.

5.4 Performance Data

Biocompatibility Testing

The biocompatibility evaluation for the Bovine Pericardial Tissue Patch device was conducted in accordance with the FDA Guidance for the Use of International Standard ISO 10993-1,"Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", June 16, 2016. Biocompatibility evaluation as required for Implant Devices, Circulating Blood Contact, Permanent Duration (>30 days) was considered in accordance with the cited guidance documents and standards.

Performance Testing

The following bench testing was conducted to demonstrate the substantial equivalence of the Bovine Pericardial Tissue Patch to the predicate device.

- Ultimate Tensile Strength, % Elongation
- Suture Retention Strength
- Crosslinking Validation
  - Differential Scanning Calorimetry (DSC)
  - Histology
- Glutaraldehyde Residuals
- Packaging Validation
  - Leak Test
  - Sterility Test

5.5 Conclusion

The testing conducted supports the Bovine Pericardial Tissue Patch being as safe and effective as the predicate and demonstrates that the device performs as intended. The performance testing conducted demonstrates that the Bovine Pericardial Tissue Patch performs substantially equivalent to the predicate device. Both the Bovine Pericardial Tissue Patch and the predicate device have the same intended use and technological characteristics.