November 9, 2023

DuraStat LLC
Adam Azzara
Chief Executive Officer
1101 E 6th St Unit B
Austin, Texas 78702

Re: K231277
Trade/Device Name: TissueStat
Regulation Number: 21 CFR 878.5035
Regulation Name: Nonabsorbable Expanded Polytetrafluoroethylene Surgical Suture
Regulatory Class: Class II
Product Code: NBY
Dated: May 2, 2023
Received: May 3, 2023

Dear Adam Azzara:

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,

Alexander Nguyen -S
2023.11.09 16:43:36 -05'00'

for 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

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)*
K231277

Device Name
TissueStat PTFE (polytetrafluroethylene) Suture and Delivery Device

Indications for Use *(Describe)*
The TissueStat PTFE (polytetrafluroethylene) Suture and Delivery Device is indicated for use in all types of soft tissue approximation and / or ligation, including cardiovascular, dental, general surgical procedures and repair of the dura mater. TissueStat PTFE Sutures are not indicated for use in microsurgery, ophthalmic procedures, or peripheral neural tissues. TissueStat PTFE Sutures are provided sterile as a single use device.

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.

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510(k) Summary
K231277

I. SUBMITTER

DuraStat, LLC
1101 E 6th St Unit B
Austin, TX USA 78702

Phone: 1 (800) 804-8018
Fax: 1 (800) 804-8018

Contact Person: Adam Azzara
Date Prepared: October 26, 2023

II. DEVICE

Name of Device: TissueStat™ PTFE (polytetrafluoroethylene) Suture and Delivery Device
Common or Usual Name: PTFE Nonabsorbable Surgical Sutures; Needle, Needle Guide and Knot Pusher
Classification Name: Suture, Surgical, Nonabsorbable, Expanded, Polytetrafluoroethylene, 878.5035; Manual Surgical Instruments for General Use, 878.4800
Regulatory Class: II
Product Code: NBY

III. PREDICATE DEVICE

DuraStat® Gazelle PTFE Suture and Delivery Device (K173335) formerly DuraTap Gazelle PTFE Suture and Delivery Device.

Reference Devices: Riverpoint Medical MonoTex ® PTFE Suture (K140415) and (K100006)

IV. DEVICE DESCRIPTION

The TissueStat PTFE surgical sutures are monofilament surgical sutures composed from expanded polytetrafluoroethylene (ePTFE) material. They are available uncoated and undyed in USP size 2/0. The sutures are attached to standard stainless steel surgical needles. The TissueStat Suture Delivery Device is a Class I Manual Surgical Instrument that assists with suture placement. The PTFE suture is loaded into the Suture Delivery Device and is delivered to the desired location through the device tip by pressing the actuation button on the device handle.

V. INDICATIONS FOR USE

The TissueStat PTFE (polytetrafluoroethylene) Suture and Delivery Device are indicated for use in all types of soft tissue approximation and / or ligation, including cardiovascular, dental, general surgical procedures and repair of the dura mater. TissueStat PTFE Sutures are not indicated for use in microsurgery, ophthalmic procedures, or peripheral neural tissues. TissueStat PTFE Sutures are provided sterile as a single use device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Attribute	**Predicate** DuraStat (Gazelle) (K173335)	**Subject Device** TissueStat (K223489)	**Comparison**
Manufacturer	DuraStat LLC	DuraStat LLC	Equivalent
Class	II	II	Equivalent
Product Code	NBY	NBY	Equivalent
Indication	The TissueStat PTFE (polytetrafluoroethylene) Suture and Delivery Device are indicated for use in all types of soft tissue approximation and / or ligation, including cardiovascular, dental, general surgical procedures and repair of the dura mater. TissueStat PTFE Sutures are not indicated for use in microsurgery, ophthalmic procedures, or peripheral neural tissues. TissueStat PTFE Sutures are provided sterile as a single use device.	The TissueStat PTFE (polytetrafluoroethylene) Suture and Delivery Device are indicated for use in all types of soft tissue approximation and / or ligation, including cardiovascular, dental, general surgical procedures and repair of the dura mater. TissueStat PTFE Sutures are not indicated for use in microsurgery, ophthalmic procedures, or peripheral neural tissues. TissueStat PTFE Sutures are provided sterile as a single use device.	Equivalent
Delivery Device Materials	ABS; Delrin; Nitinol; Stainless Steel	ABS; Delrin; Nitinol; Stainless Steel	Equivalent
Suture Material	PTFE (polytetrafluoroethylene)	PTFE (polytetrafluoroethylene)	Equivalent
Suture Size	5/0 and 6/0	2/0	Different
Needle Material	302 Stainless Steel	302 Stainless Steel	Equivalent
Device Characteristics	Suture delivery device has a distal curved tip	Suture delivery device has an elongated distal	Different

	with a needle and attached suture retained within the tip. Depressing the Delrin button releases the stylet rod which deploys the needle from the tip.	curved tip that includes a distal brace for rigidity with a needle and attached suture retained within the tip. Depressing the primer at the proximal end of the device loads the spring with a known force. Depressing the Delrin button releases the stylet rod which deploys the needle from the tip.	
Packaging (Implant contacting)	HDPE	HDPE	Same
Packaging (Whole Kit)	HDPE	HDPE and PETG	Different
Primary Sterile Barrier	Tyvek (1059B)/Polyethylene Peel Pouch.	Tyvek (1059B)/Polyethylene Peel Pouch.	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Sterilization Assurance	10^{-6}	10^{-6}	Same
Single Use	Yes	Yes	Same

DuraStat (formerly Gazelle) and TissueStat are both manufactured by DuraStat LLC and have similar technical characteristics and surgical use steps. The TissueStat device utilizes a larger suture, expanding the versatility of the tissue approximation technology with identical indications for use. Minor modifications to the needle and device characteristics facilitate the addition of the larger suture.

The following technological characteristics remain the same between the two devices.

- Device, suture, and needle materials
- Procedural steps and principles of operation
- Sterilization and delivery method

The following technological differences exist between the subject and predicate devices:

- Suture Size: Larger 2/0 Suture allows for approximation and/or ligation of soft tissue that require larger/stronger sutures with the same indications for use as the predicate.
- Needle Characteristics: Minor changes to the needle allow for approximation and/or ligation of thicker, soft tissue with the larger 2/0 suture compared to the predicate device.

- Delivery Device Characteristics: The larger 2/0 suture and associated needle are accommodated by an elongated tip with a brace that allows for easy removal for the device after the suture needle is deployed. The updated button deployment enhances ergonomics while facilitating post-deployment needle/suture positioning.
- Packaging: The device's internal packaging was changed to a Tyvek lidded tray from a backer card to improve the appearance of the packaging and to facilitate easier device removal while providing more support to the device.

These differences do not raise new questions of safety and effectiveness and were assessed by the standardized verification and validation testing described below.

VII. PERFORMANCE DATA

The following performance testing was conducted in support of the substantial equivalence determination.

Mechanical Testing

- Suture Diameter Testing per USP <861>
- Suture Tensile Testing per USP <881>
- Needle Attachment Testing per USP <871>

Biocompatibility Testing

PTFE suture is an implant with permanent (>30days) contact with tissue. A Biocompatibility Risk Assessment was conducted in accordance with ISO 10993, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process (2018) and the FDA Guidance "Use of International Standard ISO 10993- 1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process" (2020).

VIII. CONCLUSIONS

Based on the indications for use, technological characteristics, and performance testing in comparison to the predicate device, the TissueStat PTFE Suture and Delivery Device has been shown to be substantially equivalent to the legally marketed predicate device for its intended use.