April 28, 2025

Suturion AB
% Adam Harris
Senior Director, Regulatory and Strategic Development
Target Health
110 West 40th Street, 8th Floor
New York, New York 10018

Re: K250977
Trade/Device Name: Suture-TOOL System
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable Polydioxanone Surgical Suture
Regulatory Class: Class II
Product Code: NEW, GAB
Dated: March 28, 2025
Received: March 31, 2025

Dear Adam Harris:

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,

TEK N. LAMICHHANE -S

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.

510(k) Number *(if known)*
K250977

Device Name
Suture-TOOL System

Indications for Use *(Describe)*
The Suture-TOOL System is intended for abdominal wall closure after laparotomy in patients 18 years old and older.

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.

510(k) Summary (K250977)

1. APPLICANT/CONTACT

Suturion AB

Contact Person

Adam Harris, MM, RAC
Senior Director, Regulatory and Strategic Development
Target Health
110 West 40th Street, 8th Floor
New York, NY 10018
Telephone: (646) 479-2437
aharris@targethealth.com

Date of Summary: April 28, 2025

2. DEVICE

Device Proprietary Name	**Suture-TOOL System**
Classification name	Absorbable polydioxanone surgical suture
Product Code	NEW
Regulation	21 CFR 878.4840
Device Classification	Class II
Review Panel	General & Plastic Surgery

3. PREDICATE

Predicate Device	**K242835 Suture-TOOL System**	Absorbable polydioxanone surgical suture

4. DESCRIPTION OF DEVICE

The Suture-TOOL System is a single-use, sterile, suture applicator with a polydioxanone resorbable suture pre-mounted to the needle. The polydioxanone monofilament synthetic absorbable sutures are prepared from polyester, poly(p-dioxanone). The empirical molecular formula of the polymer is as follows:

-(O-CH2-CH2-O-CH2-CO)n-

The sutures are dyed with D&C Violet No. 2 (21CFR§ 74.3602).

The Suture-TOOL System includes the following:

- Polydioxanone resorbable suture pre-mounted on the needle – 1055S, 1020S (Suture&Needle).

- Suture-TOOL – 1018S (suture applicator)

Before use, the user must follow the instructions to attach the needle, preloaded with the suture, to the applicator.

5. INDICATIONS FOR USE

The Suture-TOOL System is intended for abdominal wall closure after laparotomy in patients 18 years old and older.

6. COMPARISON WITH THE PREDICATE DEVICE - SUMMARY

The Subject and Predicate devices are identical. The Subject device adds the size USP 0 suture which has the same material, design, intended use and technological characteristics as the predicate device K242835. The Subject and Predicate devices both provide sterile, single-use applicators with the same manufacturing process. The device characteristics comparing the Subject device to the Predicate device are summarized below.

Table 1: REGULATORY INFORMATION COMPARISON

Predicate Device	**Subject Device**
K242835 Suture-TOOL System	**K250977 Suture-TOOL System**
Absorbable polydioxanone surgical suture	Same
NEW	Same
21 CFR 878.4840	Same
Class II	Same
General & Plastic Surgery	Same

Table 2: OVERALL SUBSTANTIAL EQUIVALENCE COMPARISON

	Subject Device	**Predicate Device**
	Suture-TOOL System (Suture and Applicator)	**Suture-TOOL System (Suture and Applicator)**
Manufacturer	Suturion, AB	Suturion, AB
510(k) Number	K250977	K242835
	Absorbable polydioxanone surgical suture	Same
Product Code	NEW	Same
Regulation	21 CFR 878.4840	Same
Device Class	II	Same
	Suture applicator	Same
Product Code	GAB	Same
Regulation	21 CFR 878.4800	Same
Device Class	Class 1	Same
Intended Use	The Suture-TOOL System is intended for abdominal wall closure after laparotomy in patients 18 years old and older.	Same
Device Description	The Suture-TOOL System is a single-use, sterile, suture applicator with a polydioxanone resorbable suture pre-mounted to the needle. The polydioxanone monofilament synthetic absorbable sutures are prepared from the polyester, poly(p-dioxanone). The Suture-TOOL System includes the following: 1) Polydioxanone resorbable suture pre-mounted on the needle – 1055S, 1020S (Suture&Needle) and2) 2) Suture-TOOL – 1018S (suture applicator). Before use, the user must follow the instructions to attach the needle, preloaded with the suture, to the applicator.	The Suture-TOOL System is a single-use, sterile, suture applicator with a polydioxanone resorbable suture pre-mounted to the needle. The polydioxanone monofilament synthetic absorbable sutures are prepared from the polyester, poly(p-dioxanone). The Suture-TOOL System includes the following: 1) the Suture-TOOL suture applicator (1018S), and 2) a polydioxanone resorbable suture pre- mounted on the needle (1020S). Before use, the user must follow the instructions to attach the needle, preloaded with the suture, to the applicator

	Subject Device	Predicate Device
	Suture-TOOL System (Suture and Applicator)	**Suture-TOOL System (Suture and Applicator)**
Suture material	Resorbable	Same
Chemical	Poly(p-dioxanone)	Same
USP sizes	2-0, 0	2-0
Approx. Tensile strength residual at time:	4 weeks 71.7% 8 weeks 16.5%	Same
Absorption	~ 180-210 days post-implantation	Same
Needle	Double-pointed AISI 316 L	Same
Sterility	Ethylene Oxide gas	Same

7. PERFORMANCE TESTING

Physical testing was performed on the poly(p-dioxanone) synthetic absorbable suture PDO USP 0 to USP 29, including <861> suture diameter, <871> suture attachment, <881>tensile strength.

- 6-415 USP 41-NF36:2018 <881> Tensile Strength
- 6-416 USP 41-NF36:2018 <861> Sutures - Diameter
- 6-417 USP 41-NF36:2018 <871> Sutures - Needle Attachment

In all cases, the USP criteria were met or exceeded.

Design Verification/Validation

Verification testing performed with the Suture-TOOL System assessed design control to confirm the specification requirements established. The testing demonstrated that the Suture-TOOL System meets all specifications according to device requirements.

8. CONCLUSION

The Subject and Predicate devices are identical, that is, as there are no differences in technological characteristics or performance characteristics between the Subject and Predicate devices. Thus, the Sponsor has determined that the Suture-Tool System does not raise new questions of safety and effectiveness in comparison to the Predicate device and is substantially equivalent to the Predicate device.