January 22, 2025

Suturion AB
% Adam Harris
Senior Director, Regulatory and Strategic Development
Target Health LLC
450 Commerce Boulevard
Carlstadt, New Jersey 07072

Re: K242835
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
Dated: December 20, 2024
Received: December 23, 2024

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

Digitally signed by Tek N. Lamichhane -S
Date: 2025.01.22 15:36:00 -05'00'

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)*
K242835

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

1. APPLICANT/CONTACT

Suturion AB

Contact Person

Adam Harris, MM, RAC
Senior Director, Regulatory and Strategic Development
Target Health LLC
450 Commerce Boulevard
Carlstadt, NJ 07072
Phone: (646) 479-2437
aharris@targethealth.com

Date of Summary: January 22, 2025

2. DEVICE

Device Proprietary Name	**K242835 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 AND REFERENCE DEVICE

Predicate Device	K150553 Filbloc
Reference Device	K180701 SafePath Suturing System

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) and are available in size 2.

The Suture-TOOL System includes the following:

- Polydioxanone resorbable suture pre-mounted on the needle -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 AND REFERENCE DEVICES - SUMMARY

Table 1: OVERALL SUBSTANTIAL EQUIVALENCE COMPARISON

	Subject Device	**Predicate Device**	**Reference Device**
	Suture-TOOL System (Applicator and Suture)	**Filbloc Smooth or Barbed (Suture)**	**SafePath Suturing System (Applicator and Suture)**
Manufacturer	Suturion, AB	Assut Europe SpA	SafePath Medical, Inc.
510(k) Number	K242835	K150553	K180701
	Absorbable polydioxanone surgical suture	Absorbable polydioxanone surgical suture	
Product Code	NEW	NEW	
Regulation	21 CFR 878.4840	21 CFR 878.4840	
Device Class	II	II	
	Suture applicator		Suture applicator
Product Code	GAB		GAB
Regulation	21 CFR 878.4800		21 CFR 878.4800
Device Class	Class 1		Class 1
Intended Use/ Indications for Use	The Suture-TOOL System is intended for abdominal wall closure after laparotomy in patients 18 years old and older.	Filbloc sutures are indicated for use in general soft tissue approximation where use of an absorbable suture is appropriate.	The SafePath Suturing System is intended for use in placement of a silk suture in the skin and subcutaneous tissues.

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) 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.	Filbloc (polydioxanone) monofilament synthetic absorbable sutures are prepared from the polyester, poly(p dioxanone). The device is designed with unidirectional or bidirectional barbs, or with unidirectional barbs and final block in PDO. The barbs and the block design allow for tissue approximation, without need to tie surgical knot. The device is available in various lengths and diameter sizes 2 through 4/0 with various needles attached at one end or to both ends.	The silk suture provided with the SafePath Suturing System is a nonabsorbable, sterile, surgical suture composed of the organic protein, fibroin. This protein is derived from the domesticated species Bombyx mori (8. mori) of the family Bombycidae. The silk suture is silicone coated, braided and dyed (black) with logwood extract. The silk suture meets all requirements established by the United States Pharmacopeia (USP) for Nonabsorbable Surgical Suture and is available in USP size 2-0. The suture is provided as a 30 in. length, swaged on a single-armed ½ circle, 26 mm reverse cutting needle. The suture is pre-loaded in a hand-held, manually operated suturing device. When the suturing device is actuated a single stitch is placed through the tissue and the needle is automatically captured and reset for placement of an additional stitch. Finished devices may be packaged individually, or in multi-unit cartons or procedure packs. The SafePath Suturing System is designed to place a suture in skin and subcutaneous tissue. The System Includes: (2) Suturing Device Pre-loaded with one (1) 30 in. strand of USP size 2-0 black braided silk suture Swaged on a½ circle, 26 mm reverse cutting needle
Suture material	Resorbable	Resorbable	
Chemical	Poly(p-dioxanone)	Poly(p-dioxanone)	

USP sizes	2-0	4-0 to 2	
Approx. Tensile strength residual at time:	4 weeks 71.7% 8 weeks 16.5%	4 weeks 71.7% 8 weeks 16.5%	
Absorption	~ 180-210 days post-implantation	~ 180-210 days post-implantation	
Needle	Double-pointed AISI 316 L	AISI 316 L	
Sterility	Ethylene Oxide gas	Ethylene Oxide gas	

Table 2: Comparison Summary

Characteristics	**Subject**	**Predicate**	**Reference**
	Suture-TOOL System (Applicator and Suture)	**Filbloc Smooth or Barbed (Suture)**	**SafePath Suturing System (Applicator and Suture)**
	K242835	**K150553**	**K180701**
Suturing system	Yes	No	Yes
Includes suture applicator	Yes	N/A	Yes
Product code GAB	Yes	N/A	Yes
Regulation 21 CFR 878.4800	Yes	N/A	Yes
Applicator provided sterile for single-patient-use.	Yes	N/A	Yes
Absorbable polydioxanone surgical suture	Yes	Yes	No
Regulation 21 CFR 878.4840	Yes	Yes	N/A
Product code NEW	Yes	Yes	N/A
Same suture manufacturer, materials, specifications, formulation, processing, sterilization and geometry	Yes	Yes	N/A
Sutures are dyed with D&C Violet No. 2	Yes	Yes	N/A

Suture passes all required tests for USP absorbable suture material	Yes	Yes	N/A

7. PERFORMANCE TESTING

Physical testing was performed on the poly(p-dioxanone) synthetic absorbable suture, 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.

Biocompatibility Testing

Biocompatibility evaluations were performed for the Suture-TOOL System components and parts in accordance with the requirements set out in 10993-1:2018 "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

The Suture-TOOL system met the test criteria for each of the studies conducted.

Human Factors Testing

Usability/Human Factors testing was completed for the Suture-TOOL System in accordance with the Agency's Guidance for Industry, Applying Human Factors and Usability Engineering to Medical Devices 2016. Users in the study completed tasks successfully with favorable results regarding design, safety and documentation.

Literature

Two nonclinical performance studies, (Börner and Montgomery, 2020; and Börner et al., 2022) were completed with the subject device. Studies showed that the use of the subject device provided a much higher adherence to the SL/WL ratio ≥ 4 compared with manual NDS, reducing the risk for incisional hernia and site infections for patients, reducing the risk of needle stick injuries for surgeons.

Comparison of Significant Features

- The Subject and Predicate devices provide identical absorbable polydioxanone surgical sutures using the same manufacturer, materials, specifications, formulation, processing, sterilization and geometry.
- The Subject and Reference devices are both systems intended for

the placement of sutures.

- The Subject and Reference devices both provide sterile, single-use applicators with the same regulation and product code.

8. CONCLUSION

The comparison tables, discussion and the testing provided all demonstrate that the Suture-TOOL System meets its specifications, fulfils its intended use, and is substantially equivalent to the Predicate device. 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.