October 18, 2024

SafePath Medical, Inc.
Howard Schrayer
Regulatory Consultant
8 Lookout
Hilton Head Island, South Carolina 29928

Re: K222944
Trade/Device Name: SafePath Suturing System-Silk Suture, SafePath Suturing System Polyamide Suture (Nylon), SafePath Suturing System- Polypropylene Suture
Regulation Number: 21 CFR 878.5030
Regulation Name: Natural Nonabsorbable Silk Surgical Suture
Regulatory Class: Class II
Product Code: GAP, GAR, GAW
Dated: May 22, 2023
Received: May 23, 2023

Dear Howard Schrayer:

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: 2024.10.18 13:01:04 -04'00'

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)*
K222944

Device Name
SafePath Suturing System – Silk Suture
SafePath Suturing System – Polyamide (Nylon) Suture
SafePath Suturing System – Polypropylene Suture

Indications for Use *(Describe)*

SafePath Suturing System – Silk Suture
The SafePath Suturing System is intended for use in placement of a silk suture in the skin and subcutaneous tissues.

SafePath Suturing System – Polyamide (Nylon) Suture
The SafePath Suturing System is intended for use in placement of a nylon suture in the skin and subcutaneous tissues.

SafePath Suturing System – Polypropylene Suture
The SafePath Suturing System is intended for use in placement of a polypropylene suture in the skin and subcutaneous tissues.

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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510(k) SUMMARY – K222944
(Per 21 CFR 807.92)

General Company Information

Name: SafePath Medical, Inc.
Contact: Howard Schrayer
Regulatory Affairs Consultant

Address: 21 Water Street - 5th Floor
Amesbury, MA 01913

Telephone: 978-697-3267

Date Prepared October 16, 2024

General Device Information

Product Name: SafePath Suturing System – Silk Suture

Classification: Silk Suture
Product code: GAP – Class II
Regulation: 21 CFR 878.5030

Product Name: SafePath Suturing System – Polyamide (Nylon) Suture

Classification: Nylon Suture
Product code: GAR – Class II
Regulation: 21 CFR 878.5020

Product Name: SafePath Suturing System -Polypropylene Suture

Classification: Polypropylene Suture
Product code: GAW – Class II
Regulation: 21 CFR 878.5010

Classification: Suture Passer
Product code: GAB - Class I
Regulation: 21 CFR 878.4800

Predicate Devices

Primary Predicate

SafePath Medical	SafePath Suturing System (with silk suture and suture passer) [510(k) K180701]

Secondary Predicate Devices

SM ENG CO Ltd.	REXLON® Nylon Suture [510(k) K161633]
SM ENG CO Ltd.	REXLENE® Polypropylene Suture [510(k) K173747]

Description

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 (B. 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 36 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.

The nylon suture provided with the SafePath Suturing System is a nonabsorbable, sterile, surgical suture composed of long chain aliphatic polymers - nylon 6,6. SafePath nylon sutures are dyed with Logwood extract, FDA approval number §73.1410. The nylon suture meets all requirements established by the United States Pharmacopeia (USP) for Nonabsorbable Surgical Suture and is available in USP sizes 2-0 and 3-0. The suture is provided as a 36 in. length, swaged to 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.

The polypropylene suture provided with the SafePath Suturing System is a monofilament synthetic non-absorbable, sterile surgical suture composed of an isotactic crystalline stereoisomer of polypropylene, a synthetic linear polyolefin. The molecular formula is $(C_3H_6)_n$. The Safepath suture is dyed with [Phthalocyaninato(2-)] copper, FDA approval number §74.3045. The polypropylene suture meets all requirements established by the United States Pharmacopeia (USP) for Nonabsorbable Surgical Suture and is available in USP sizes 2-0 and 3-0. The suture is provided as a 36 in. length, swaged to 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.

Intended Use / Indications for Use

SafePath Suturing System – Silk Suture
The SafePath Suturing System is intended for use in placement of a silk suture in the skin and subcutaneous tissues.

SafePath Suturing System – Polyamide (Nylon) Suture
The SafePath Suturing System is intended for use in placement of a nylon suture in the skin and subcutaneous tissues.

SafePath Suturing System – Polypropylene Suture
The SafePath Suturing System is intended for use in placement of a polypropylene suture in the skin and subcutaneous tissues.

Substantial Equivalence

A table comparing the SafePath device with a predicate silk suture is provided below. This submission supports the position that the SafePath Suturing System is substantially equivalent to previously cleared devices, including those listed above. A number of predicate devices list the same clinical use.

SUBSTANTIAL EQUIVALENCE INFORMATION

Predicate Devices	**SafePath Medical, Inc.**
SafePath Suturing System - K180701 REXLON Nylon Suture – K161633 REXLENE Polypropylene Suture K173747	**SafePath Suturing System K222944**

Similarities and Differences

Silk suture is indicated for use in skin and subcutaneous tissue and other soft tissue applications, excluding use in cardiovascular and neural tissue	SafePath silk suture is indicated for use in skin and subcutaneous tissue.
REXLON is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular or neural tissue.	SafePath nylon suture is indicated for use in skin and subcutaneous tissue.
REXLENE is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular or neural tissue.	SafePath polypropylene suture is indicated for use in skin and subcutaneous tissue.

Regulation: 21 CFR 878.5030 Regulation: 21 CFR 878.5020 Regulation: 21 CFR 878.5010	Regulation: 21 CFR 878.5030 Regulation: 21 CFR 878.5020 Regulation: 21 CFR 878.5010
Product code: GAP – Class II Product code: GAR – Class II Product code: GAW – Class II	Product code: GAP – Class II Product code: GAR – Class II Product code: GAW – Class II
Suture is provided with and without pre-attached (swaged) needle	Suture is provided with pre-attached (swaged) needle
Suture implant component is non-absorbable.	Suture implant component is non-absorbable.
Device is provided sterile for single-patient-use.	Device is provided sterile for single-patient-use.
Suture is provided without a suture passer component	Suture is pre-loaded in manually operated suturing device
Silk suture is dyed black with logwood extract and coated with silicone for lubricity	Silk suture is dyed black with logwood extract and coated with silicone for lubricity
Nylon suture is dyed black with logwood extract	Nylon suture is dyed black with logwood extract
Polypropylene suture is dyed blue with ([Phthalocyaninato (2-)] Copper)	Polypropylene suture is dyed blue with ([Phthalocyaninato (2-)] Copper)
Suture material is manufactured by Ashaway Line & Twine Mfg. Co.	Suture material is manufactured by Ashaway Line & Twine Mfg. Co.
Suture is provided with swaged, stainless steel needle	Suture is provided with swaged, stainless steel needle
Suture passes all required tests for USP non-absorbable suture material and needle attachment	Suture passes all required tests for USP non-absorbable suture material and needle attachment
Silk suture is braided	Silk suture is braided
Nylon suture is monofilament	Nylon suture is monofilament
Polypropylene suture is monofilament	Polypropylene suture is monofilament

Performance Testing – Non-Clinical

Physical Testing

Non-clinical testing has been performed in accordance USP (United States Pharmacopeia) Nonabsorbable Sutures – Diameter, Sutures- Needle Attachment, and Tensile Strength. In all cases, the USP criteria were met or exceeded.

Biocompatibility Testing

The biocompatibility evaluation for the SafePath Suturing System (with silk suture and the suture passer) was referenced from the previously cleared SafePath submission K180701. For the nylon and polypropylene sutures, the safety evaluation was conducted based on the following considerations: (i)The nylon and polypropylene sutures are made from identical raw materials as the predicate device. (ii) The packaging and sterilization conditions are the same as those used for the predicate device. (iii) The manufacturing information from raw materials to the packaging was leveraged from the primary predicate device (K180701) for the silk suturing system.

A risk assessment was conducted on the raw materials and manufacturing processes for the nylon and polypropylene sutures to evaluate the safety of the device. The additional safety information was leveraged from the previously cleared K180701 submission.

For those tests conducted, the battery of testing included the following evaluations:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Hemocompatibility
- Pyrogenicity
- Endotoxicity

The SafePath Suturing System met the test criteria for each of the studies.

Conclusions

SafePath Medical, Inc. believes that the information provided establishes that similar legally marketed devices including the referenced predicate devices, have been used for the same clinical application as the SafePath Medical SafePath Suturing System.

The safety and performance of the subject devices have been evaluated and found to be substantially equivalent to the referenced predicate devices.