June 25, 2018

SafePath Medical, Inc.
Mr. Howard Schrayer
Official Correspondent
21 Water Street - 5th Floor
Amesbury, Massachusetts 01913

Re: K180701
Trade/Device Name: SafePath Suturing System
Regulation Number: 21 CFR 878.5030
Regulation Name: Natural Nonabsorbable Silk Surgical Suture
Regulatory Class: Class II
Product Code: GAP
Dated: May 24, 2018
Received: May 25, 2018

Dear Mr. 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 (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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K180701

Device Name
SafePath™ Suturing System

Indications for Use *(Describe)*
The SafePath Suturing System is intended for use in placement of a silk 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.

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510(k) SUMMARY
(Per 21 CFR 807.92)

General Company Information

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

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Amesbury, MA 01913

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Date Prepared March 15, 2018

General Device Information

Product Name: SafePath Suturing System

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

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

Predicate Devices

SM ENG CO Ltd.	REXSIL® Silk Suture [510(k) K161633]
Ethicon, Inc.	USP non-absorbable silk suture PMA N11397
Louisville Laboratories, Inc.	Carter-Thomason Needle-Point Suture Passer [510(k) K980123]

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 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 a ½ circle, 26 mm reverse cutting needle

Intended Use (Indications)

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

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 was conducted in accordance with FDA Guidance regarding the use of International Standards ISO-10993.

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.

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.

SM ENG CO Ltd. REXSIL® Silk Suture 510(k) K161633	**SafePath Medical, Inc. SafePath Suturing System TBD**
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	Silk suture is indicated for use in skin and subcutaneous tissue
Regulation: 21 CFR 878.5030	Regulation: 21 CFR 878.5030
Product code: GAP – Class II	Product code: GAP – Class II
Suture is provided with and without pre-attached (swaged) needle	Suture is provided with pre-attached (swaged) needle
Silk suture implant component is non-absorbable.	Silk 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

Suture is dyed black with logwood extract and coated with silicone for lubricity	Suture is dyed black with logwood extract and coated with silicone for lubricity
Braided suture material is manufactured by Ashaway Line & Twine Mfg. Co.	Braided 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

Conclusions

SafePath Medical , Inc. believes that the information provided establishes that similar legally marketed devices have been used for the same clinical application as the SafePath Medical SafePath Suturing System. The materials from which the SafePath Medical device is fabricated have an established history of use, and the devices have been developed in accordance with applicable FDA guidelines.