July 7, 2020

Sm Eng Co., Ltd
% Sanglok Lee
Manager
Wise Company Inc.
#303, 142, Gasan digital 1-ro
Geumcheon-gu, 08507 Kr

Re: K200392
Trade/Device Name: Rexsin
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM
Dated: June 4, 2020
Received: June 11, 2020

Dear Sanglok Lee:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200392

Device Name
REXSIN

Indications for Use *(Describe)*
REXSIN 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.

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.

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TEL.82-51-305-8016 FAX.82-51-305-8021

510(k) Summary

The assigned 510(k) Number: K200392

Date of Submission: February 12, 2020

Applicant

Company name: SM ENG CO., LTD
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Subject Device Identification

Proprietary Name: REXSIN
Common Name: Synthetic Absorbable PGA Suture With or Without Needle
Device Class: Class II
Regulation Number:21 C.F.R. 878.4493
Product Code: GAM
Classification Name: Suture, Absorbable, Synthetic, Polyglycolic Acid

Indication for use

REXSIN 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

Predicate devices

510(k) Number: K073614
Device Name: WG-Surgical Sutures with Needle
Manufacturer: FOOSIN MEDICAL SUPPLIES INC.LTD

Device Description

Synthetic Absorbable PGA Suture With or Without Needle (REXSIN) are produced and provided by SM ENG Co., Ltd. REXSIN 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

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Suture of REXSIN is Trisorb manufactured by SAMYANG Biopharmaceuticals Corporation. SM Eng is receiving bulk Trisorb from Samyang, and then go through cutting, adhesion of need and thread, winding and sterilization process according to SM Eng procedure, which becomes REXSIN suture.

REXSIN is a sterilized medical device composed with absorbable, braided, coated suture with needle, stainless steel SUS 304

REXSIN Suture is a synthetic absorbable, braided, coated suture composed of a Polyglycolic acid (PGA). The suture is available undyed (natural) or dyed (D&C Violet No.2). Approximately over 65% of tensile strength remain after 2week. Complete absorption in tissues takes around 90 days.

REXSIN Sutures meets requirements established by the United States Pharmacopoeia (USP) for Absorbable Surgical Sutures. REXSIN Sutures is available in 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1 and 2, which are the sizes identified in the currently recognized United States.

Non-Clinical Test Conclusion

Bench tests were conducted to verify that the subject device (REXSIN) met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the subject device complies with the following standards:

USP <861> SUTURES - DIAMETER
USP <871> SUTURES – NEEDLE ATTACHMENT
USP <881> TENSILE STRENGTH
USP MONOGRAPH OF ABSORBABLE SURGICAL SUTURE

Sterile barrier system testing
ISO 11607-1, Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements For Materials, Sterile Barrier Systems And Packaging Systems
ISO 11607-2, Packaging For Terminally Sterilized Medical Devices - Part 2: Validation Requirements For Forming, Sealing And Assembly Processes
ASTM F 88, Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F 1929, Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration

Accelerated aging stability testing
- ASTM F 1980, Standard Guide For Accelerated Aging Of Sterile Barrier Systems For Medical Devices. (Sterility)

Biocompatibility testing
1) Suture Needle
- ISO 10993-12: Sample Preparation
- ISO 10993-5: Test for Cytotoxicity
- ISO 10993-10: Test for Irritation and Sensitization
2) Suture
- ISO 10993-1: Selection of Tests

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- ISO 10993-2: Animal Welfare
- ISO 10993-12: Sample Preparation
- ISO 10993-5: Test for Cytotoxicity
- ISO 10993-10: Test for Irritation and Sensitization
- ISO 10993-11: Test for Systemic Toxicity
- ISO 10993-3: Tests for Genotoxicity
- ISO 10993-6: Test for Local Effects after Implantation
- ISO 10993-4: Selection of Tests for Interaction with Blood

Real-time and accelerated aging stability testing was performed to support shelf life of REXSIN. Additionally, the residual strength and absorption rate studies were evaluated in accordance with the requirements outlined in FDA's Class II Special Controls Guidance Document: Surgical Sutures.

Substantially Equivalent Conclusion

The following table compares the subject device (REXSIN) to the predicate devices with respect to intended use, technological characteristics and principles of operation, etc.

Table. Comparison of Technology Characteristics

Property	Subject device: REXSIN	Predicate device: WG-Surgical Sutures with Needle
510(k) Number	K200392	K073614
Product Code	GAM	Same
Indications for use statements	REXSIN 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.	Same
Class	II	Same
Sterile	Yes	Same

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Single Use	Yes	Same
Configuration	PGA Suture and Needle	Same
Suture		
Material	Polyglycolic acid	Same
Coating material	Polycaprolactone and Calcium stearate	Same
Color	Undyed (natural) and dyed (D&C Violet No.2)	Same
Absorbable/Nonabsorbable	Absorbable	Same
Braided/Monofilament	Braided	Same
Barbed/Not Barbed	Not Barbed	Same
Suture Size	The subject device is available in 8-0, 7-0, 6-0, 5-0, 4-0,3-0,2-0, 0, 1 and 2., which are the sizes identified in the currently recognized United States Pharmacopoeia.	Same. The subject device is available in 10-0 through 3 or 4, which are the sizes identified in the currently recognized United States Pharmacopoeia.
Length of Suture	15, 30, 45, 50, 60, 75, 90, 100, 120, 125, 140, 250cm	Unknown

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Diameter of Suture	The tensile strengths of subject device comply with the tensile requirement listed in USP <861>	Same
Tensile strength	The tensile strengths of subject device comply with the tensile requirement listed in USP <881>	Same
Needle Attachment	The bond between suture and needle of the applicant device meet the requirements defined in USP <871>.	Same
Needle		
Material	Stainless Steel	Same
Needle type	Taper point, Reverse Cutting, Conventional cutting, Taper cutting, Spatula, Blunt point	Unknown
Biocompatibility	Comply with ISO 10993-5, 10993-10	Same

The subject devices, REXSIN are determined to be Substantially Equivalent (SE) to the predicate device, and as safe and effective as the predicate device.