December 21, 2018

Sm Eng Co., Ltd
% Sanglok Lee
Manager
Wise Company Inc.
#1005, 11-19, Gamasan-ro 27a-gil
Guro-gu, 08301 Kr

Re: K173747
Trade/Device Name: Rexlene
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable Polypropylene Surgical Suture
Regulatory Class: Class II
Product Code: GAW
Dated: September 1, 2018
Received: September 19, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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 Digitally signed by David Krause -S Date: 2018.12.21 12:36:59 -05'00'

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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K173747

Device Name
REXLENE

Indications for Use *(Describe)*
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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

006-1

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

006-1

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510(k) Summary

The assigned 510(k) Number: K173747

01. Date of Submission: December 14, 2017

02. Applicant

Company name: SM ENG CO., LTD
Address: 46, Nakdong-daero 1302beon-gil, Sasang-gu, Busan, Korea
TEL: +82 51 3058016
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Email: leesg@sm-eng.net

03. Submission Correspondent

Sanglok, Lee
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Email: info@wisecompany.org

04. Proposed Device Identification

Proprietary Name: REXLENE
Common Name: Synthetic Nonabsorbable Polypropylene Suture With or Without Needle
Device Class: Class II
Regulation Number: 21 C.F.R. 878.5010
Product Code: GAW
Regulation Description: Nonabsorbable polypropylene surgical suture

05. Indication for use

REXLENE is indicated for use in general soft tissue approximation and/or ligation, including use in tophthalmic procedures, but not for use in cardiovascular or neural tissue.

06. Predicate devices

-Primary Predicate Device
510(k) Number: K080684
Device Name: , WG-Surgical Sutures with Needle
Manufacturer: FOOSIN MEDICAL SUPPLIES INC.LTD

-Reference Predicate Device

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510(k) Number: K133356
Device Name: PROLENETM Polypropylene Nonabsorbable Suture
Manufacturer: ETHICON, Inc

07. Device Description

REXLENE is a sterilized nonabsorbable monofilament surgical suture made out of polypropylene used in general soft tissue approximation and/or ligation with or without needle made out of Stainless Steel STS 304.

REXLENE suture is a nonabsorbable, sterile surgical monofilament suture composed of polypropylene. REXLENE sutures are not coated. The sutures are dyed blue to enhance visibility in tissue.

REXLENE suture meets all requirements established by the United States Pharmacopoeia (U.S.P.) for nonabsorbable surgical suture. Available suture size is as below.
- Dyed suture blue ([Phthalocyaninato (2-)] Copper): USP 8-0 ~ USP 1

08. Non-Clinical Test Conclusion

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

USP <861> SUTURES - DIAMETER

USP <871> SUTURES – NEEDLE ATTACHMENT

USP <881> TENSILE STRENGTH
USP Nonabsorbable Surgical Suture
Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.

Real-time and accelerated aging stability testing was performed to support shelf life of REXLENE. Testing confirmed that the sutures conform to USP requirements for non-absorbable sutures and are stable over the proposed shelf life.

Raw suture of REXLON were evaluated in accordance with ISO 10993 standards below, they are biocompatible and suitable to use as medical device.
ISO 10993, Biological Evaluation of Medical Devices Including:
- 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

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09. Summary of Technological characteristic of subject and predicate devices.

Property	Subject device REXLENE	Primary Predicate Device WG-Surgical Sutures with Needle	Reference Predicate Device PROLENETM Polypropylene Nonabsorbable Suture
510(k) Number	K173747	K080684	K133356
Product Code	GAW	Same	Same
Regulation No,	21 C.F.R. 878.5010	Same	Same
Class	II	Same	Same
Sterile	Yes	Same	Same
Single Use	Yes	Same	Same
Indications for use statements	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	Nonabsorbable Polypropylene Suture with Needle is indicated for use in general soft tissue approximation and/or ligation including use in cardiovascular, ophthalmic and neurological procedures.	PROLENEYm suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.
Configuration	Polypropylene Suture and Needle	Same	Same

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Suture			
Material	Polypropylene	Polypropylene	Polypropylene
Coating	uncoated	same	same
Color	Blue dyed	same	same
Absorbable/Nonabsorbable	Nonabsorbable	same	same
Braided/Monofilament	Monofilament	same	same
Suture Size	The proposed device is available in 8-0 through 1, which are the sizes identified in the currently recognized United States Pharmacopoeia.	Available suture sizes (USP 10-0 ~ USP 2) are standard according to USP requirements	Available suture (USP 10-0 ~ USP 2) sizes are standard according to USP requirements except for USP size 7-0
Length of Suture	13, 15, 45, 50, 60, 70, 75, 90, 100, 120, 180 cm	Unknown	Unknown
Diameter of Suture	The suture diameters of proposed device comply with the diameter requirement listed in USP <861> Diameter.	same	Meet the requirements defined in the USP except for USP size 7-0
Tensile strength	The tensile strengths of proposed device comply with the tensile requirement listed in USP <881> Tensile Strength	same	Meet the requirements defined in the USP except for USP size 7-0

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Needle Attachment	The bond between suture and needle of the applicant device meet the requirements defined in USP <871>.	same	Meet the requirements defined in the USP except for USP size 7-0
Sterilization method	Ethylene oxide gas sterilization	same	same
Needle			
Material	Stainless Steel	Same	same
Indication for use	Disposable suturing needle	Same	Same
Needle Tip Geometry (Needle type)	Taper point, Tapper cut Spatula, Reverse cutting,	Same. Taper point Tapper cut Conventional cutting Reverse Cutting Extra-Sharp cutting Blunt Spatula	Same. Based on Ethicon's catalog, they provide ATRALOC needles to surgeons. Surgeon select type of needle that, in their experience, is appropriate for the specific procedure and Needle shapes are generally classified according to the degree of curvature of the body and needle type – 1/2, 3/8, 1/4, 5/8, straight – Tapper point, Blunt point, Conventional cutting, Reverse Cutting, Spatula, Micro point
Circle (Shape)	1/2, 3/8, straight	Same. 1/2, 3/8, 1/4, 5/8, Straight, Ski Needle, Compound curve	

10. Substantially Equivalent Conclusion

The proposed device, REXLENE is determined to be Substantially Equivalent **(SE)** to the predicate devices in respect of safety and effectiveness.