DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 2, 2017

SM ENG CO., Ltd
% Mr. Sanglok Lee
Wise Company, Inc.
#306, 3 Daerim-ro 27ga-gil
Yeongdeungpo-gu, 07413 KR

Re: K161633
Trade/Device Name: REXLON®, REXSIL®
Regulation Number: 21 CFR 878.5020
Regulation Name: Nonabsorbable polyamide surgical suture
Regulatory Class: Class II
Product Code: GAR, GAP
Dated: January 24, 2017
Received: January 31, 2017

Dear Mr. 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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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

510(k) Number *(if known)*

K161633

Device Name
REXLON

Indications for Use *(Describe)*
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.

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)*

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006-2

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)*

K161633

Device Name

REXSIL

Indications for Use *(Describe)*

REXSIL 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)

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510(k) Summary

The assigned 510(k) Number: K161633

Date of Submission: January 24, 2017

Applicant

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

1. Nylon Monofilament Suture With or Without Needle

1.1 Proposed Device Identification

Proprietary Name: REXLON
Common Name: Nonabsorbable Polyamide Suture With or Without Needle
Device Class: Class II
Regulation Number: 21 C.F.R. 878.5020
Product Code: GAR
Device Classification Name: Suture, Nonabsorbable, Synthetic, Polyamide

1.2 Indication for use

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.

1.3 Predicate devices

Predicate device 01
510(k) Number: K080684
Device Name: WG-Surgical Sutures with Needle
Classification Name: Suture, Nonabsorbable, Synthetic, Polyamide
Manufacturer: FOOSIN MEDICAL SUPPLIES INC.LTD.

Predicate device 02
510(k) Number: K982646
Device Name: Reli
Classification Name: SUTURE, NONABSORBABLE, SYNTHETIC, POLYAMIDE
Manufacturer: AILEE CO LTD.

1.4 Device Description

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

REXLON suture is a nonabsorbable, sterile surgical monofilament suture composed of the long-chain aliphatic polymers Nylon 6 and Nylon 6,6. REXLON sutures are not coated. The sutures are dyed black (Logwood) or blue (FD&C Blue No.2) to enhance visibility in tissue. The suture is also available undyed (Natural).

REXLON 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 Black (Logwood): USP 11-0 ~ USP 1
- Dyed suture Blue (FD&C Blue No.2): USP 8-0 ~ USP 2
- Undyed suture (Natural): USP 8-0 ~ USP 1

1.5 Non-Clinical Test Conclusion

USP 35 <861> SUTURES - DIAMETER
USP 35 <871> SUTURES - NEEDLE ATTACHMENT
USP 35 <881> TENSILE STRENGTH
USP Nonabsorbable Surgical Suture
ASTM F88-09. Standard Test Method for Seal Strength of Flexible Barrier Materials;
ASTM F1929-98(2004) Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration
USP <71> STERILITY TEST
USP 36, <151>; Pyrogen Test
ISO 11135-1:2007 Sterilization of health care products- Ethylene oxide- Part 1: Requirements for development, validation and routing control of a sterilization process for medical devices;
USP <85> Bacterial Endotoxin Limit;
ISO 10993, Biological Evaluation of Medical Devices: Including:
Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)
Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2002, including Amd 1:2006)
Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)

Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2007)
Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008)
Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)
Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2006)

REXLON were evaluated in accordance with the listed tests above.
Real-time and accelerated aging stability testing was performed to support shelf life of REXLON. Testing confirmed that the sutures conform to USP requirements for non-absorbable sutures, are biocompatible per ISO 10993-1, and are stable over the proposed shelf life

1.6 Substantially Equivalent Conclusion

Table 1: Substantial Equivalence Comparison

Property	Proposed device REXLON	Predicate device 01 WG-Surgical Sutures with Needle	Predicate device 02 Reli
510(k) Number	K161633	K080684	K982646
Product Code	GAR	GAR	GAR
Regulation No,	21 C.F.R. 878.5020	21 C.F.R. 878.5020	21 C.F.R. 878.5020
Class	II	II	II
Sterile	Yes	Yes	Yes
Single Use	Yes	Yes	Yes
Intended use	Indication for use is in general soft tissue approximation and/or ligation, including use in ophthalmic procedures,	Indication for use is in general soft tissue approximation and/or ligation, including use in ophthalmic procedures.	Indication for use as non absorbable sutures is in general soft tissue approximation and/or ligation, including use in

	but not for use in cardiovascular or neural tissue.		cardiovascular, ophthalmic, neural tissue.
Configuration	Nonabsorbable Polyamide Suture With Needle	Nonabsorbable Polyamide Suture With Needle	Nonabsorbable Polyamide Suture With Needle
Suture			
Raw Suture Material	polyamide surgical suture from long-chain aliphatic polymers Nylon 6 and Nylon 6,6	polyamide surgical suture from long-chain aliphatic polymers Nylon 6 and Nylon 6,6	polyamide surgical suture from long-chain aliphatic polymers Nylon 6 and Nylon 6,6
Suture Manufacturer	Ashaway Line & Twine Mfg. Co.	Pearsalls Limited	Ashaway Line & Twine Mfg. Co.
Color (Colorant)	Dyed suture Black (Logwood), Blue (FD&C Blue No.2) and Undyed suture (Natural)	Dyed suture Black (Logwood), Blue & phthalocyanine blue (FD&C Blue No.2) and Undyed suture (Natural)	Dyed suture Black (Logwood), Blue (FD&C Blue No.2) and Undyed suture (Natural)
Coating material	Not used	Not used	Not used
Absorbable/Nonabsorbable	Nonabsorbable	Nonabsorbable	Nonabsorbable
Braided/Monofilament	Monofilament	Monofilament	Monofilament
Suture Size	Available suture sizes are standard according to USP requirements Available suture size is as below. #1 Dyed suture Black (Logwood): USP 11-0~USP 1 #2 Dyed suture Blue (FD&C Blue No.2): USP 8-0~USP 2 #3 Undyed suture (Natural): USP 8-0~USP 1	Available suture sizes are standard according to USP requirements	Available suture sizes are standard according to USP requirements

Length of Suture	15cm, 20cm, 30cm, 35cm, 40cm, 45cm, 50cm 60cm, 70cm, 75cm, 80cm, 100cm, 150cm, 200cm	Unknown	15cm, 20cm, 30cm, 45cm, 50cm
Diameter of Suture	The suture diameters of proposed device comply with the diameter requirement listed in U5P 35 <861> Diameter.	The suture diameters of proposed device comply with the diameter requirement listed in U5P 35 <861> Diameter.	Meet the requirements defined in the USP
Tensile strength	The tensile strengths of proposed device comply with the tensile requirement listed in U5P 35 <881> Tensile Strength	The tensile strengths of proposed device comply with the tensile requirement listed in U5P 35 <881> Tensile Strength	Meet the requirements defined in the USP
Needle Attachment	The bond between suture and needle of the applicant device meet the requirements defined in USP 35 <871>.	The bond between suture and needle of the applicant device meet the requirements defined in USP 35 <871>.	Meet the requirements defined in the USP
Needle			
Material	Stainless Steel	Stainless Steel	Stainless Steel
Needle type	Reverse Cutting, Taper point, Spatula	Taper, cutting, spatual, blund ,taper cut, diamond, premimum cutting and square	Spatula, taper point, Blunt point

The proposed device, **REXLON**, is determined to be Substantially Equivalent **(SE)** to the predicate device, WG-Surgical Sutures with Needle (K080684) and Reli (K982646) in respect of safety and effectiveness.

2. Nonabsorbable Silk Suture With or Without Needle

2.1 Proposed Device Identification

Proprietary Name: REXSIL
Common Name: Nonabsorbable Braided Silk Suture With or Without Needle
Device Class: Class II
Regulation Number: 21 C.F.R. 878.5030
Product Code: GAP
Device Classification Name: Suture, Nonabsorbable, Silk

2.2 Indication for use

REXSIL 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.

2.3 Predicate devices

Predicate device 01
510(k) Number: K080684
Device Name: WG-Surgical Sutures with Needle
Classification Name: SUTURE, NONABSORBABLE, SILK
Manufacturer: FOOSIN MEDICAL SUPPLIES INC.LTD

Predicate device 02
510(k) Number: K982646
Device Name: Reli
Classification Name: SUTURE, NONABSORBABLE, SILK
Manufacturer: AILEE CO LTD.

2.4 Device Description

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

REXSIL suture is a nonabsorbable, sterile, surgical suture composed of an organic protein call fibroin. This protein is derived from the domesticated species Bombyx mori (b. More) of the family Bombycidae. REXSIL sutures are processed to remove the natural waxes and gums. REXSIL suture is dyed black (Logwood) and coated with silicone. REXSIL suture is also available undyed (Natural).

REXSIL 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 Black (Logwood): USP 8-0 ~ USP 2
- Undyed suture (Natural): USP 7-0 ~ USP 2

2.5 Non-Clinical Test Conclusion

USP 35 <861> SUTURES - DIAMETER
USP 35 <871> SUTURES - NEEDLE ATTACHMENT
USP 35 <881> TENSILE STRENGTH
USP Nonabsorbable Surgical Suture
ASTM F88-09. Standard Test Method for Seal Strength of Flexible Barrier Materials;
ASTM F1929-98-98 Standard Test Method for Detecting Seal Leaks in Porous Medical

Package by Dye Penetration
USP <71> STERILITY TEST
USP <151>; Pyrogen Test
ISO 11135-1:2007 Sterilization of health care products- Ethylene oxide- Part 1: Requirements for development, validation and routing control of a sterilization process for medical devices;
USP <85> Bacterial Endotoxin Limit;
ISO 10993, Biological Evaluation of Medical Devices:
Including:
Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)
Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2002, including Amd 1:2006)
Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2007)
Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008)
Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)
Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2006)

REXSIL were evaluated in accordance with the listed tests above.
Real-time and accelerated aging stability testing was performed to support shelf life of REXSIL. Testing confirmed that the sutures conform to USP requirements for non-absorbable sutures, are biocompatible per ISO 10993-1, and are stable over the proposed shelf life

2.6 Substantially Equivalent Conclusion

Table 1: Substantial Equivalence Comparison

Property	Proposed device REXSIL	Predicate device 01 WG-Surgical Sutures with Needle	Predicate device 02 Reli
510(k) Number	K161633	K080684	K982646
Product Code	GAP	GAP	GAP
Regulation No,	21 C.F.R. 878.5030	21 C.F.R. 878.5030	21 C.F.R. 878.5030

Class	II	II	II
Sterile	Yes	Yes	Yes
Single Use	Yes	Yes	Yes
Configuration	Nonabsorbable Silk Suture and Needle	Nonabsorbable Silk Suture and Needle	Nonabsorbable Silk Suture
Suture			
Raw Suture Material	Silk suture	Silk suture	Silk suture
Suture Manufacturer	Ashaway Line & Twine Mfg. Co.	Pearsalls Limited	Ashaway Line & Twine Mfg. Co.
Coating material	Silicone coated	Silicone and wax coated	Silicone coated
Color (Colorant)	Dyed suture Black (Logwood) and Undyed suture (Natural)	Dyed suture Black (Sulphol or Logwood) and Undyed suture (Natural)	Dyed suture Black (Logwood) and Undyed suture (Natural)
Absorbable/Nonabsorbable	Nonabsorbable	Nonabsorbable	Nonabsorbable
Braided/Monofilament	Braided	Braided	Braided
Suture Size	Available suture sizes are standard according to USP requirements Available suture size is as below. #1 Dyed suture Black (Logwood): USP 8-0 ~	Available suture sizes are standard according to USP requirements	Available suture sizes are standard according to USP requirements

	USP 2 #2 Undyed suture (Natural): USP 7-0 ~ USP 2		
Length of Suture	30cm, 35cm, 40cm, 45cm, 50cm, 55cm, 60cm, 70cm, 75cm, 100cm, 110cm, 150cm, 180cm,	Unknown	Unknown
Diameter of Suture	The suture diameters of proposed device comply with the diameter requirement listed in USP 35 <861> Diameter.	The suture diameters of proposed device comply with the diameter requirement listed in USP 35 <861> Diameter.	Meet the requirements defined in the USP
Tensile strength	The tensile strengths of proposed device comply with the tensile requirement listed in USP 35 <881> Tensile Strength	The tensile strengths of proposed device comply with the tensile requirement listed in USP 35 <881> Tensile Strength	Meet the requirements defined in the USP
Needle Attachment	The bond between suture and needle of the applicant device meet the requirements defined in USP 35 <871>.	The bond between suture and needle of the applicant device meet the requirements defined in USP 35 <871>.	Meet the requirements defined in the USP
Needle			
Material	Stainless Steel	Stainless Steel	Stainless Steel
Needle type	Reverse Cutting, Taper point, Spatula	Taper point, Reverse Cutting, Conventional cutting, Taper cutting, Spatula, Blunt point	Spatula, taper point,

The proposed device, **REXSIL**, is determined to be Substantially Equivalent **(SE)** to the predicate device, WG-Surgical Sutures with Needle (K080684) and Reli (K982646) in respect of safety and effectiveness.