March 12, 2018

SM ENG CO., LTD
% Sanglok Lee
Manager
Wise COMPANY Inc.
#1005, 11-19, Gamasan-ro 27a-gil
Guro-gu, Seoul, Korea

Re: K173779
Trade/Device Name: REXMONO, PDREX
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM, NEW
Dated: November 11, 2017
Received: December 12, 2017

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. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

510(k) Number *(if known)*
K173779

Device Name
REXMONO, PDREX

Indications for Use *(Describe)*
REXMONO 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.

PDREX is indicated for use in all types of soft tissue approximation, including use in cardiovascular tissue where growth is expected to occur, PDO suture is not indicated in adult cardiovascular tissue, microsurgery, ophthalmic and 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)*

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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WISE COMPANY Inc.

#1005, 11-19, Gamasan-ro 27-gil,

Guro-gu, Seoul, Republic of Korea
Tel: +82 2 831 3615
info@wisecompany.org

510(k) Summary

The assigned 510(k) Number: K173779

- **Date of Preparation: March 05, 2018**

- **Sponsor Identification**

Company name: SM ENG CO., LTD
Address: 46, Nakdong-daero 1302beon-gil, Sasang-gu, Busan, Korea
TEL: +82 51 3058016
FAX: +82 513058021
Email: leesg@sm-eng.net

Establishment Registration Number: 3008912461

- **Submission Correspondent**

Sanglok, Lee
Wise COMPANY Inc.
#1005, 11-19, Gamasan-ro 27-gil, Guro-gu, Seoul, Korea
TEL: +82 70 8812 3619 / +82 2 831 3615
FAX: +82 50 4031 3619
Email: info@wisecompany.org

WISE COMPANY Inc.
와이즈컴퍼니(주)

WISE COMPANY Inc.

#1005, 11-19, Gamasan-ro 27-gil,

Guro-gu, Seoul, Republic of Korea
Tel: +82 2 831 3615
info@wisecompany.org

● Proposed Device Identification

1. REXMONO

Device Identification and Regulatory information

Proprietary Name: REXMONO
Common Name: Synthetic Absorbable PGA-PCL Monofilament Suture With or Without Needle
Device Class: Class II
Regulation Number: 21 C.F.R. 878.4493
Product Code: GAM

Indications for Use

REXMONO 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. PDREX

Device Identification and Regulatory information

Proprietary Name: PDREX
Common Name: Synthetic Absorbable Monofilament Polydioxanone Suture With or Without Needle
Device Class: Class II
Product Code: NEW

Indications for Use

PDREX is indicated for use in all types of soft tissue approximation, including use in cardiovascular tissue where growth is expected to occur, PDO suture is not indicated in adult cardiovascular tissue, microsurgery, ophthalmic and neural tissue.

● Predicate Device Identification

1. REXMONO

-Predicate Device
510(k) Number: K142810
Device Name: WEGO-PGCL Absorbable Surgical Monofilament Suture
Manufacturer: FOOSIN MEDICAL SUPPLIES INC.LTD

2. PDREX

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

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와이즈컴퍼니(주)

WISE COMPANY Inc.
#1005, 11-19, Gamasan-ro 27-gil,
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info@wisecompany.org

● Device Description

1. REXMONO

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

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

REXMONO is a sterilized medical device composed with absorbable monofilament suture, poly (glycolide-co-caprolactone), with needle, stainless steel SUS 304.

REXMONO Suture is a synthetic absorbable, monofilament, suture composed of poly (glycolide-co-caprolactone). The suture is available undyed (natural) or dyed (D&C Violet No.2). Approximately 68~78% of tensile strength remain after 1 week. Complete absorption in tissues takes around 90 to 110 days.

REXMONO Sutures are U.S.P. except for diameters in the following sizes:

MAXIMUM SUTURE OVERSIZE IN DIAMETER (mm) FROM U.S.P.

U.S.P. SUTURE SIZE DESIGNATION	MAXIMUM OVERSIZE (mm)
6-0	0.050
5-0	0.050
4-0	0.050
3-0	0.090
2-0	0.060
0	0.100
1	0.071
2	0.011

2. PDREX

Synthetic Absorbable Monofilament Polydioxanone Suture With or Without Needle (PDREX) are produced and provided by SM ENG Co., Ltd. PDREX is indicated for use in all types of soft tissue approximation, including use in cardiovascular tissue where growth is expected to occur, PDO suture is not indicated in adult cardiovascular tissue, microsurgery, ophthalmic and neural tissue.

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와이즈컴퍼니(주)

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

PDREX is a sterilized medical device composed with polydioxanone surgical suture, with needle, stainless steel SUS 304.

PDREX Suture is a synthetic absorbable, monofilament, suture composed of a Poly (p-dioxanone). The suture is available dyed (D&C Violet No.2). Approximately 50~60% of tensile strength remain after 6 week. Complete absorption in tissues takes around 180 to 210 days.

PDREX Sutures are U.S.P. except for diameters in the following sizes:

MAXIMUM SUTURE OVERSIZE IN DIAMETER (mm) FROM U.S.P.

U.S.P. SUTURE SIZE DESIGNATION	MAXIMUM OVERSIZE (mm)
7-0	0.025
6-0	0.050
5-0	0.050
4-0	0.050
3-0	0.090
2-0	0.060
0	0.100
1	0.071
2	0.011

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● Non-Clinical Test Conclusion (REXMONO & PDREX)

Bench tests were conducted to verify that the proposed device (REXMONO & PDREX) 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 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
- 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 REXMONO. Additionally, the residual strength and absorption rate studies were demonstrated and the sutures were evaluated in accordance with the requirements outlined in FDA's Class II Special Controls Guidance Document: Surgical Sutures

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● Substantially Equivalent Conclusion

The following table compares the REXMONO and PDREX to the predicate devices with respect to intended use, technological characteristics and principles of operation, etc.

Table. Comparison of Technology Characteristics

REXMONO			**PDREX**		
Property	Proposed device: REXMONO	Predicate device: WEGO-PGCL Absorbable Surgical Monofilament Suture	**Property**	Proposed device: PDREX	Predicate device: WG-Surgical Sutures with Needle
510(k) Number	K173779	K142810	**510(k) Number**	K173779	K073614
Product Code	GAM	Same	**Product Code**	NEW	Same
Indications for use statements	REXMONO 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. The WEGO-PGCL Absorbable Surgical Monofilament Suture is indicated for use in general soft tissue approximation and/or, but not for use in cardiovascular or neurological procedure	**indications for use statements**	PDREX 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	Absorbable Polydioxanone Suture with Needle is indicated for use in all types of soft tissue approximation, including use in cardiovascular tissue where growth is expected to occur, PDO suture is not indicated in adult cardiovascular tissue,

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					microsurgery, ophthalmic and neural tissue.
Class	II	Same	**Class**	II	Same
Sterile	Yes	Same	**Sterile**	Yes	Same
Single Use	Yes	Same	**Single Use**	Yes	Same
Configuration	PGA-PCL Suture and Needle	Same	**Configuration**	Polydioxanone Suture and Needle	Same
Suture					
Material	Poly(glycolide–co-caprolactone)) copolymer	Same	**Material**	Poly (p-dioxanone)	Same
Coating material	None	Same	**Coating material**	None	None
Color	Undyed (natural) and dyed (D&C Violet No.2)	Same	**Color**	Dyed (D&C Violet No.2).	Violet or Undyed
Absorbable/ Nonabsorbable	Absorbable	Same	**Absorbable/ Nonabsorbable**	Absorbable	Absorbable
Braided/Monofilament	Monofilament	Same	**Braided/Monofilament**	Monofilament	Monofilament

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Barbed/Not Barbed	Not Barbed	Same	**Barbed/Not Barbed**	Not Barbed	Same
Suture Size	The proposed device is available in 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. Sutures are U.S.P. except for diameters. All suture sizes are oversized	Similar. The proposed device is available in 6-0, 5-0, 4-0,3-0,2-0, 0, and 1, which are the sizes identified in the currently recognized United States Pharmacopoeia. Sutures are U.S.P. except for diameters. All suture sizes are over sized	**Suture Size**	The proposed device is available in 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. Sutures are U.S.P. except for diameters. All suture sizes are oversized	Same
Length of Suture	30, 45, 50, 60, 70, 75, 90, 150, 250cm	30cm, 45cm, 60cm, 75cm, 90cm, 100cm, 120cm, 150cm, 180cm, 200cm, 250cm, 280cm, 300cm, 320cm, 360cm and 390cm	**Length of Suture**	20, 23, 30, 35, 45, 60, 70, 75, 90, 150cm	Not known
Diameter of Suture	Oversize	Oversize	**Diameter of Suture**	Oversize	Same
Tensile strength	The tensile strengths of proposed device comply	Same	**Tensile strength**	The tensile strengths of proposed device comply	Same

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	with the tensile requirement listed in USP <881> Tensile Strength			with the tensile requirement listed in USP <881> Tensile Strength	
Needle Attachment	The bond between suture and needle of the applicant device meet the requirements defined in USP <871>.	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	**Material**	Stainless Steel	Same
Needle type	Taper point, Reverse Cutting, Conventional cutting, Taper cutting, Spatula, Blunt point	Similar. Taper, Cutting, Blunt	**Needle type**	Taper point, Reverse Cutting, Conventional cutting, Taper cutting, Spatula, Blunt point	Similar. Not known
Biocompatibility	Comply with ISO 10993-5 and ISO 10993-10	Same	**Biocompatibility**	Comply with ISO 10993-5 and ISO 10993-10	Same

The proposed devices, REXMONO & PDREX, are determined to be Substantially Equivalent (SE) to the predicate devices.