DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 10, 2017

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

Re: K161629
Trade/Device Name: CRYLREX®
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM
Dated: December 28, 2016
Received: January 5, 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,

Jennifer R. Stevenson -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)*

K161629

Device Name
CRYLREX®

Indications for Use *(Describe)*
CRYLREX® 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)*

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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510(k) Summary

The assigned 510(k) Number: K161629

01. Date of Submission: 2016.12.28

02. Applicant

Company name: SM ENG CO., LTD
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03. Submission Correspondent

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04. Proposed Device Identification

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

05. Indication for use

CRYLREX® is indicated for use in general soft tissue approximationand/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular or neural tissue.

06. Predicate devices

Predicate device 01
510(k) Number:K130735
DeviceName: WEGO-PGLA Absorbable Surgical Suture
Classification Name: Suture, Absorbable, Synthetic, Polyglycolic Acid
Manufacturer: FOOSIN MEDICAL SUPPLIES INC.LTD

07. Device Description

CRYLREX® is a sterilized medical device composed with multifilament absorbable, braided, coated suture, 90% glycolide and 10% L-lactide, with needle, stainless steel SUS 304.

CRYLREX® Suture is a synthetic absorbable, braided, coated suture composed of a copolymer made from 90% glycolide and 10% L-lactide and is available both dyed and

undyed. CRYLREX® Suture is coated with poly(glycolideco-lactide)(30/70) and calcium stearate. The suture is available undyed (natural) or dyed (D&C Violet No.2). Approximately 75% of tensile strength remain after 2 weeks, 50% of tensile strength remain after 3 weeks. Complete absorption in tissues takes around 56 to 70 days.

CRYLREX® 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)
8-0	0.007
7-0	0.010
6-0	0.021
5-0	0.036
4-0	0.031
3-0	0.036
2-0	0.021
0	0.056
1	0.046
2	0.031

08. Non-Clinical Test Conclusion

Bench 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 proposeddevice complies with the following standards:

USP 35 <861> SUTURES - DIAMETER
USP 35 <871> SUTURES - NEEDLE ATTACHMENT
USP 35 <881> TENSILE STRENGTH
USP Absorbable Surgical Suture
Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA
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 fordevelopment, 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 reproductivetoxicity (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)

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

09. Substantially Equivalent Conclusion

Table 1: Substantial Equivalence Comparison

Property	Proposed device CRYLREX®	Predicate device 01 WEGO-PGLA Absorbable Surgical Suture
510(k) Number	K161629	K130735
Product Code	GAM	Same
Regulation No,	2 1 CFR 878.4493	Same
Class	II	Same
Sterile	Yes	Same
Single Use	Yes	Same
Configuration	PGLA Suture and Needle	Same

Suture		
Raw Suture Material	Neosorb	Same
Manufacturer of Raw Suture Material	Samyang Biopharmaceuticals Corporation	Same
Final Material Composition	90% glycolide and 10% L-lactide (PGLA)	Same
Coating material	Poly(glycolide-co-lactide) (30/70)+ Calcium Stearate	Same
Color (Colorant)	Undyed (natural) or Dyed (D&C Violet No.2)	Same
Absorbable/Nonabsorbable	Absorbable	Same
Braided/Monofilament	Braided	Same
Suture Size	The proposed 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 except for diameter	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 except for diameter
Length of Suture	20cm, 30cm, 45cm, 60cm, 70cm, 75cm, 90cm, 100cm, 125cm, 140cm, 150cm, 250cm,	30cm, 45cm, 60cm, 75cm, 90cm, 100cm, 120cm, 150cm,l80cm, 200cm, 250cm, 280cm, 300cm, 320cm, 360cmand 390cm
Diameter of Suture	Oversize	Oversize
Tensile strength	The tensile strengths of proposed device comply with thetensile requirement listed in USP 35 <881> TensileStrength	The tensile strengths of proposed device comply with thetensile requirement listed in USP 35 <881> TensileStrength

Needle Attachment	The bond between suture and needle ofthe applicantdevice meet the requirements defined in USP 35 <871>.	The bond between suture and needle ofthe applicantdevice meet the requirements defined in USP 35 <871>.
Needle		
Material	Stainless Steel	Stainless Steel
Needle type	Taper point, Reverse Cutting, Conventional cutting, Taper cutting, Spatula, Blunt point	Taper, Spatula, Cutting, Blunt

The proposed device, **CRYLREX® Suture**, is determined to be SubstantiallyEquivalent **(SE)** to the predicate device, SYNTHETIC ABSORBABLE SUTURE (K130735) in respect of safety and effectiveness.