August 5, 2022

Samyang Holdings Corp., Ltd.
% Sanglok Lee
Manager
Wise Company Inc.
#507,#508 166, Gasan digital 2-ro
Geumcheon-gu, Seoul 08503
Korea, South

Re: K212810
Trade/Device Name: MONOFIX PGCL, knotless wound closure device
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM
Dated: August 30, 2021
Received: September 3, 2021

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 and Part 809 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,

for Deborah Fellhauer, RN, BSN
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212810

Device Name
MONOFIX PGCL, knotless wound closure device

Indications for Use *(Describe)*
MONOFIX PGCL, knotless wound closure device is indicated for use in soft tissue approximation where the use of absorbable suture is appropriate. MONOFIX PGCL, knotless wound closure device should not be used to approximate tissue under tension and the use of barbed suture has not been shown to be safe in the closure of hernias, laparotomy incisions, bowel anastomosis or suture lines, vascular suture lines, and vaginal cuff closure in controlled clinical or preclinical studies for minimally invasive or open surgery.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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The assigned 510(k) Number: K212810

01. Date of Submission: 05.20.2022

02. Applicant

Company name: Samyang Holdings Corp., Ltd.
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03. Submission Correspondent

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04. Subject Device Identification

Trade Name: MONOFIX PGCL, knotless wound closure device
Common Name: Absorbable PGA-PCL surgical suture with needle
Classification Name: Absorbable poly(glycolide/l-lactide) surgical suture
Product Code: GAM
Panel: General and Plastic Surgery Devices
Regulation Number: 21 CFR 878.4493
Device Class: II

05. Indication for use

MONOFIX PGCL, knotless wound closure device is indicated for use in soft tissue approximation where the use of absorbable suture is appropriate. MONOFIX PGCL, knotless wound closure device should not be used to approximate tissue under tension and the use of barbed suture has not been shown to be safe in the closure of hernias, laparotomy incisions, bowel anastomosis or suture lines, vascular suture lines, and vaginal cuff closure in controlled clinical or preclinical studies for minimally invasive or open surgery.

06. Predicate devices

Predicate device
510(k) Number: K141778
Device Name: Quill™ Monoderm™ Knotless Tissue-Closure(PGA-PCL), Variable Loop Design
Manufacturer: Surgical Specialties Corporation

Reference device
510(k) Number: K182873
Device Name: STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device
Manufacturer: Ethicon

07. Device Description

MONOFIX PGCL, knotless wound closure device, comprised of Poly(glycolide-co-ε-carprolactone)(PGA-PCL) is a synthetic absorbable monofilament undyed-suture. It is available sterile, developed by Samyang Holdings Corp., Ltd. The MONOFIX PGCL, knotless wound closure device consists of a Barb-type suture and a surgical needle, with a suture at one end and a stopper shaped end for tissue anchoring at the other end. The stopper is attached to the end of the suture and has a triangular shape with one side length of 1.8 to 3.3 mm and a thickness of 0.7 to 1.0 mm. The device is designed with small uni-directional barbs in size 0.18~0.55 mm along

the length and stopper that eliminate the need to tie knots during approximation. The device is available in lengths of 15 to 60cm and diameter sizes 1 through 3-0 with needles in 1/2 circle, 3/8 circle, 5/8 circle, 1/2 curved and straight shapes attached to each end.

08. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the subject device met all design specifications. The test results demonstrated that the subject device complies with the following standards:

Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA
USP <861> Suture Diameter
USP <871> Suture-Needle attachment
USP <881> Tensile Strength Surgical Suture
USP Monographs: Absorbable Surgical Suture
EP Monographs: Sutures, Sterile Synthetic Absorbable Monofilament

Sterilization
ISO 11135:2014, Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 10993-7, Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals

Sterile barrier system testing
ASTM F 88, Standard Test Method for Seal Strength of Flexible Barrier Materials

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 10993-5: Test for Cytotoxicity
- ISO 10993-10: Test for Irritation and Sensitization
- ISO 10993-11: Test for Systemic Toxicity
- ISO 10993-4: Selection of tests for interactions with blood
- ASTM F756-17: Standard Practice for Assessment of Hemolytic Properties of Materials

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 interactions with blood
- ASTM F756-17: Standard Practice for Assessment of Hemolytic Properties of Materials
- In vivo tensile strength of Monofix PGCL was performed to evaluate the tensile strength retention rate.

09. Substantially Equivalent Conclusion

Table 1: Substantial Equivalence Comparison

Product Name	Subject Device	Predicate Device	Reference Device	Equivalence Discussion
510(k) Number	k212810	K141778	K182873	
Product Code	GAM	GAM	GAM	same
Indications for use statements	MONOFIX PGCL, knotless wound closure device is indicated for use in soft tissue approximation where the use of absorbable suture is appropriate. MONOFIX PGCL, knotless wound closure device should not be used to approximate tissue under tension and the use of barbed suture has not been shown to be safe in the closure of hernias, laparotomy incisions, bowel anastomosis or suture lines, vascular suture lines, and vaginal cuff closure in controlled clinical or preclinical studies for minimally invasive or open surgery.	Quill™ MONODERM™ Device is indicated for use in soft tissue approximation where the use of absorbable sutures is appropriate.	STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device is indicated for use in soft tissue approximation where the use of absorbable sutures is appropriate.	same
Class	II	II	II	same
Sterile	Yes	Yes	Yes	same
Single Use	Single use	Single use	Single use	same
Material	Poly(glycolide-co-ε-carprolactone)(PGA-PCL)	Poly(glycolide-co-ε-carprolactone)(PGA-PCL)	Poly(glycolide-co-ε-carprolactone)(PGA-PCL)	same
Color	Undyed	Undyed, Dyed(Violet)	Undyed	Same Analysis 1
Absorbable/ Non-absorbable	absorbable	absorbable	absorbable	same
Braided/ Monofilament	Monofilament	Monofilament	Monofilament	same
Barbed/ Not Barbed	Uni-directional barbs	Uni-directional barbs	Uni-directional barbs	same
Suture Size	USP size 1 to 3-0	USP size 1 to 4-0	unknown	same
Needle Material	Stainless steel	Stainless steel	Stainless steel	same
Sterilization	EO	EO	EO	same
USP Diameter Requirements	Oversize. Suture meets requirements for “Absorbable Surgical Suture” except diameter.	Suture meets exceeds requirements for “Absorbable Surgical Suture”	Oversize. Suture meets requirements for “Absorbable Surgical Suture” except diameter.	Same Analysis 2
Tensile Strength requirements	Suture meets the performance requirements defined for “Tensile strength” <881>	Suture meets the performance requirements defined for “Tensile strength” <881>	Suture meets the performance requirements defined for “Tensile strength” <881>	same

Needle Attachment Requirements	Suture meets the performance requirements defined for “Needle Attachment” <871>	Suture meets the performance requirements defined for “Needle Attachment” <871>	Suture meets the performance requirements defined for “Needle Attachment” <871>	same

Analysis 1 – Color

The suture of predicate device is undyed and dyed. The suture of subject device is only available in undyed.
K182873 added as a reference device to support the difference in undyed characteristic.
This difference does not affect the safety and effectiveness of the product.

Analysis 2 – USP Diameter Requirements

USP designations for diameter are used to describe MONOFIX PDO Device suture after barbing except for minor variation in suture diameter with a maximum average of 0.1 mm.
The actual diameter of the non-barbed section fiber is one size greater than the designated size with a maximum overage of 0.1 mm.

The USP and EU Pharmacopoeia sizes of the Proposed Device are further defined in Table 1.

Table 1. Diameter Comparison

USP Device size Designation	EU Pharmacopoeia Device size (Metric / Ph. Eur.) Designation	MONOFIX PGCL, knotless wound closure device		
		USP	Metric / Ph. Eur.	Tensile strength size
1	4	1	4	0
0	3.5	0	3.5	2-0
2-0	3	2-0	3	3-0
3-0	2	3-0	2	4-0

STRATAFIX™ Spiral MONOCRYL™ Knotless Tissue Control Device is oversized barbed suture. K182873 added as a reference device to support the difference in USP Diameter characteristic.

10. Conclusion

The subject device, MONOFIX PGCL, knotless wound closure device, is determined to be Substantially Equivalent (SE) to the predicate devices, Quill™ Monoderm™ Knotless Tissue-Closure(PGA-PCL), Variable Loop Design (K141778) in respect of safety and effectiveness.