August 25, 2026

Samyang Holdings Corporation
℅ Samy Puccio
Director, IVD Global Regulatory Affairs
Rqm+
2790 Mosside Blvd., #800
Monroeville, Pennsylvania 15146

Re: K253879
Trade/Device Name: Monofix Pdo
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable Polydioxanone Surgical Suture
Regulatory Class: Class II
Product Code: NEW
Dated: July 22, 2026
Received: July 22, 2026

Dear Samy Puccio:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

TEK N. LAMICHHANE -S

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253879

Device Name
MONOFIX PDO

Indications for Use *(Describe)*
MONOFIX PDO absorbable knotless wound closure device is indicated for soft tissue approximation where the use of absorbable sutures is appropriate.

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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510(k) Summary
(K253879)

MANUFACTURER AND 510(k) OWNER

Samyang Holdings Corp., Ltd.
55, Munpyeongseo-ro, 18beon-gil, Daedeok-gu,
Daejeon, 34302, Korea
Telephone: +82-42-930-3134
Official Contact: Ahram Kim, Regulatory Affairs Manager

DATE PREPARED: August 25, 2026

REPRESENTATIVE/CONSULTANT

Samy Puccio
RQM+
Telephone: +1 (412) 816-9864
Email: spuccio@rqmplus.com

DEVICE INFORMATION

Proprietary Name/Trade Name: MONOFIX PDO
Common Name: Absorbable polydioxanone surgical suture with needle
Regulation Number: 878.4840
Device Class: II
Product Code: NEW

PREDICATE DEVICE IDENTIFICATION

MONOFIX PDO is substantially equivalent to the following predicate(s):

510(k) Number	*Predicate Device Name / Manufacturer*	*Product Code*	*Regulation Name*
K120827	Quill PDO Knotless Tissue-Closure (Polydioxanone)/ Angiotech	NEW	Absorbable Polydioxanone Surgical Suture, 21 CFR 878.4840

REFERENCE DEVICE IDENTIFICATION

510(k) Number	*Reference Device Name / Manufacturer*	*Product Code*	*Regulation Name*
K091087	V-LOC 180 ABSORBABLE WOUND CLOSURE DEVICE/ Medtronic	GAM	Absorbable poly(glycolide/l-lactide) surgical suture., 21 CFR 878.4493

DEVICE DESCRIPTION

MONOFIX PDO is an absorbable knotless wound closure device comprised of a poly-dioxanone suture. The Poly-dioxanone is a synthetic, absorbable monofilament material dyed violet (D&C Violet No. 2). It is provided sterile. MONOFIX PDO has a surgical needle at one end for soft tissue insertion and a stopper at the other end for tissue anchoring. The suture itself is a Barb-type, designed with small uni-directional barbs along the length. The barbs and stopper eliminate the need to tie knots during usage. The device is available in various lengths and diameter sizes with various stainless steel surgical needles attached to one end.

INDICATIONS FOR USE

MONOFIX PDO absorbable knotless wound closure device is indicated for soft tissue approximation where the use of absorbable sutures is appropriate.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Characteristics	**Subject Device MONOFIX PDO**	**Predicate Device Quill PDO Knotless Tissue-Closure (Polydioxanone) K120827**	**Comments**
Product Code	NEW	NEW	Same
Intended Use	Knotless tissue closure and soft tissue approximation	Knotless tissue closure and soft tissue approximation	Same
Indications for Use	MONOFIX PDO absorbable knotless wound closure device is indicated for soft tissue approximation where the use of absorbable sutures is appropriate.	Quill PDO Knotless Tissue-Closure Device, comprised of Polydioxanone, is indicated for soft tissue approximation where use of an absorbable suture is appropriate.	Similar to Predicate
Sterile	Yes	Yes	Same
Single Use	Yes	Yes	Same
Material	PDO poly(p-dioxanone)	PDO poly(p-dioxanone)	Same
Color	Dyed (Violet)	Dyed (Violet)	Same
Absorbable/ Non-absorbable	Absorbable	Absorbable	Same
Braided/ Monofilament	Monofilament	Monofilament	Same
Barbs	Uni-directional	Bi-directional	Similar
Suture Diameter Size	USP size 2 to 3-0	USP size 2 to 4-0	Size range within size range of Predicate
Length of Suture	15-60 cm	unknown	Similar
Needle Material	Stainless Steel	Stainless Steel	Same

SUMMARY OF NON-CLINICAL TESTING

Testing was performed in accordance FDA's guidance document, *"Class II Special Controls Guidance Document: Surgical Sutures – Guidance for Industry and FDA Staff" issued on June 3, 2003* and to the following standards to demonstrate safety based on current industry standards:

- USP 43-NF38 <861> Sutures – Diameter
- USP 43-NF38 <871> Sutures – Needle Attachment
- USP 43-NF38 <881> Sutures – Tensile Strength
- ISO 11135-1 Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
- ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
- Biocompatibility testing in accordance with FDA's Guidance *"Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" (Issued September 2020)*

Other testing included in-vivo tensile strength, in-vivo barb holding strength and tensile strength retention testing. The results of testing indicate that the MONOFIX PDO is substantially equivalent to the predicate device.

CONCLUSION

The MONOFIX PDO is considered substantially equivalent to the predicate devices based on the testing performed, the similar indications for use, and similar technological characteristics.