October 15, 2025

Feeltech Co., Ltd
℅ Albert Rego
Consultant
Albert Rego PhD, Inc (d.b.a Rego Associates)
25401 Cabot Road, # 122
Laguna Hills, California 92653

Re: K250107
Trade/Device Name: V-soft Line™ Barbed Surgical Suture (Various)
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable Polydioxanone Surgical Suture
Regulatory Class: Class II
Product Code: NEW
Dated: April 25, 2025
Received: April 29, 2025

Dear Albert Rego:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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
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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)*
K250107

Device Name
V-soft Line™ Barbed Surgical Suture (Various)

Indications for Use *(Describe)*
The V Soft Line with needle device comprised of dyed polydioxanone, is indicated for soft tissue approximation where use of an absorbable suture is appropriate.

The anatomical location(s) of use are on the skin for dermatological applications only. The suture is not intended for interior body cavity applications and the suture is not intended for lifting and supporting tissues.

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
(K250107)

I. SUBMITTER:

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Date Prepared: April 25, 2025

II. DEVICE:

Trade Name:	V-Soft Line™ Barbed Surgical Suture
Common Name:	Absorbable Polydioxanone Suture with Needle
Regulation Number Code:	21 CFR 878.4840
Device Class:	Class II
Panel Review:	General & Plastic Surgery
Product Code:	NEW

III. PREDICATE DEVICE:

510(k) Number:	K172602
Trade Name:	21 CFR 878.4840
Device Class:	Class II
Panel Review:	General & Plastic Surgery
Product Code:	NEW
Manufacturer:	Feeltech Co., Ltd.

IV. DEVICE DESCRIPTION:

The V-Soft Line™ synthetic absorbable PDO suture with needle is made of polydioxanone. The pigment for the violet dye is D&C Violet No.2. The V-Soft Line™ is available sterile after ethylene oxide (EO) gas sterilization and degrades or dissolves over time in tissue. The barbed sutures are pre-loaded and are not attached to the needle.

Each dyed (violet) suture has bi-directional barbs along the long axis of the suture monofilament with needle attachment. The V-Soft Line™ Synthetic Absorbable PDO suture with needle

approximates tissue without the need to tie surgical knots, by using the opposing barbs on the surface to embed in the tissues after the surgeon precisely places the suture within the tissues.

The proposed suture is available in 2, 2-0, and 3-0 suture sizes, which are the sizes identified in the currently recognized Unites States Pharmacopeia.

The V-Soft Line™ is barbed to two sections on suture and the barbs on each section are opposite direction each other. The reason that this suture has each opposite barb direction is not to slide and move to forth and back and to fix well. Therefore, the effectiveness of suture for treatment can be improved.

V. INDICATIONS FOR USE

The V-Soft Line™ barbed device comprised of dyed polydioxanone, is indicated for soft tissue approximation where use of an absorbable suture is appropriate. The anatomical location(s) of use are on the skin for dermatological applications only. The suture is not intended for interior body cavity applications and the suture is not intended for lifting and supporting tissues.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The direct comparison of the predicate device to the subject device addresses all of the physical characteristics.

The comparison of features and operation principles between V-Soft Line™ (PDO) Suture from Feeltech Co. Ltd. and Miracu™ (PDO) Barbed Surgical Suture (K172602) is listed as follows:

Category	**Subject Device** V-Soft Line™ **Barbed Surgical Suture**	**Predicate Device** **Miracu™ Barbed Surgical Suture** **(K172602)**	**Substantially Equivalent or Not Substantially Equivalent**
Common Name	Suture Absorbable Synthetic Polydioxanone with Needle Suturing Disposable	Suture Absorbable Synthetic Polydioxanone with Needle Suturing Disposable	Substantially Equivalent
Manufacturer	Feeltech Co., Ltd.	Feeltech Co., Ltd.	Not Applicable
510(k) Number	N/A	K172602	Not Applicable
Indication For Use	The V-Soft Line™ barbed surgical suture is comprised of dyed polydioxanone is indicated for soft tissue approximation where use of an absorbable suture is appropriate.	The Miracu™ barbed surgical suture is comprised of dyed polydioxanone is indicated for soft tissue approximation where use of an absorbable suture is appropriate.	<u>Indications for Use</u> Subject device, predicate device are similar with respect to usage on soft tissue approximation. Substantially Equivalent <u>Design</u>

Category	Subject Device V-Soft Line™ Barbed Surgical Suture	Predicate Device Miracu™ Barbed Surgical Suture (K172602)	Substantially Equivalent or Not Substantially Equivalent
	The anatomical location(s) of use are on the skin for dermatological applications only. The suture is not intended for interior body cavity applications and the suture is not intended for lifting and supporting tissues.	The anatomical location(s) of use are on the skin for dermatological applications only. The suture is not intended for interior body cavity applications and the suture is not intended for lifting and supporting tissues.	Similar in usage of suture type (absorbable, biodegradable) and application. Substantially Equivalent
Sterile	Ethylene Oxide	Ethylene Oxide	Substantially Equivalent
Configuration	PDO Suture and Needle. predicate suture being swaged to a standard suturing needle	PDO Suture and Needle. predicate suture being swaged to a standard suturing needle	Design Similar in usage of suture type (absorbable, biodegradable) and application. Substantially Equivalent
Materials	Poly (dioxanone)	Poly (dioxanone)	Identical Substantially Equivalent
Color	Dyed (violet)	Dyed (violet)	Identical Substantially Equivalent
Absorbable	Absorbable	Absorbable	Identical Substantially Equivalent
Braid/Monofilament	Monofilament	Monofilament	Substantially Equivalent
Suture Size	3-0, 2-0, 2,	4-0, 3-0, 2-0, 0	Design Similar in usage of suture type (absorbable, biodegradable) and application. Different in Predicate Device suture size however no impact to form, fit, function, or safety of the suture.

Category	Subject Device V-Soft Line™ Barbed Surgical Suture	Predicate Device Miracu™ Barbed Surgical Suture (K172602)	Substantially Equivalent or Not Substantially Equivalent
			Substantially Equivalent
Overall suture design	1) non-barbed section → 1st barbed section → Space between barbed sections → 2nd barbed section → non-barbed section 2) non-barbed section → 1st barbed section → Space between barbed sections 3) 1st barbed section → non-barbed section → 2st barbed section → non-barbed section → 3nd barbed section	1) non-barbed section → 1st barbed section → Space between barbed sections → 2nd barbed section → non-barbed section 2) non-barbed section → 1st barbed section → Space between barbed sections 3) 1st barbed section → non-barbed section → 2st barbed section → non-barbed section → 3nd barbed section	Substantially Equivalent
Length of Suture[1]	50mm, 80mm, 110mm, 150mm, 160mm, 180mm, 185mm	90mm, 110mm, 150mm	<u>Design</u> Similar in usage of suture type (absorbable, biodegradable) and application. Similar in suture lengths. <u>Different</u> in Predicate Device lengths however no impact to form, fit, function, or safety of the suture. Substantially Equivalent
Length of barb section (1st barbed section x 2nd barbed section)	110mm (24mmx24mm), 150mm (35mmx35mm), 150mm (20mmx29mm), 160mm (37.5mmx37.5mm),	110mm (24mmx24mm), 130mm (25mmx25mm), 150mm (35mmx35mm), 150mm (20mmx29mm), 160mm (37.5mmx37.5mm),	Substantially Equivalent

Category	Subject Device V-Soft Line™ Barbed Surgical Suture	Predicate Device Miracu™ Barbed Surgical Suture (K172602)	Substantially Equivalent or Not Substantially Equivalent
	180mm(48mmx48mm), 180mm(32mmx44mm), 185mm (35mmx47mm)	165mm(44mmx48mm), 180mm(48mmx48mm), 180mm(32mmx44mm), 185mm (35mmx47mm)	
Length of barb section (1st barbed section)	50mm (24mm), 160mm (63mm), 185mm (90mm)	50mm (24mm), 160mm (63mm), 185mm (90mm)	Substantially Equivalent
Number of barb per the linear length of suture	barbs per 10mm (various, typical, average) 2.2 barbs per 10mm 3.5 barbs per 10mm 4.5 barbs per 10mm 5 barbs per 10mm	7 barbs per 10mm	Design Similar in usage of suture type (absorbable, biodegradable) and application. Similar in suture lengths. Different in Predicate Device number of barb per unit linear length of sutures however no impact to form, fit, function, or safety of the suture. Substantially Equivalent
Barb (Cog) angle	2~45˚ 25~35 ˚ 30~40 ˚	35° ± 5°	Design Similar in usage of suture type (absorbable, biodegradable) and application. Similar in suture lengths. Different in Predicate Device barb (cog) angle however no impact to form, fit, function, or safety of the suture. Substantially Equivalent
Barb (Cog) length	Various 1.7mm ± 10%	1mm ± 0.1mm	Design

Category	Subject Device V-Soft Line™ Barbed Surgical Suture	Predicate Device Miracu™ Barbed Surgical Suture (K172602)	Substantially Equivalent or Not Substantially Equivalent
	1.1~2.3mm 1.7~2.3mm 2.7~3.3mm 4.2~4.7mm		Similar in usage of suture type (absorbable, biodegradable) and application. Similar in suture lengths. Different in Predicate Device barb (cog) length however no impact to form, fit, function, or safety of the suture. Substantially Equivalent
Barb (Cog) spacing	Various 1.8~2.2 mm 1.7~2.3 mm 2.7~3.3 mm 4.2~4.7 mm	2mm ± 0.1mm	Design Similar in usage of suture type (absorbable, biodegradable) and application. Similar in suture lengths. Different in Predicate Device interval between barb (Cog) spacing however no impact to form, fit, function, or safety of the suture. Substantially Equivalent
Interval between barbed sections	Various 3 mm 7 mm 10 mm 13.5 15 mm	10mm	Design Similar in usage of suture type (absorbable, biodegradable) and application. Similar in suture lengths. Different in Predicate Device interval between barbed sections however no impact to form, fit, function, or safety of the suture. Substantially Equivalent

Category	Subject Device V-Soft Line™ Barbed Surgical Suture	Predicate Device Miracu™ Barbed Surgical Suture (K172602)	Substantially Equivalent or Not Substantially Equivalent
Direction of barb (Cog)	Direction of barbs of 1st barbed section is reverse direction against x 2nd barbed section LSCO Type: Direction of barbs of 1st barbed section is same direction against x 2nd barbed section C-Cog Type: 1 barbed section, unidirectional Forte Fix Type: 1 barbed section, unidirectional	Direction of barbs of 1st barbed section is reverse direction against x 2nd barbed section	Design Similar in usage of suture type (absorbable, biodegradable) and application. Similar in suture lengths. Different in Predicate Device direction of barb (cog) for LSCO Type, C-Cog Type and Forte Fix Type however no impact to form, fit, function, or safety of the suture. Substantially Equivalent
Configuration of barb (Cog)	Two-way (both side) barb forming	Two-way (both side) barb forming	Design Similar in usage of suture type (absorbable, biodegradable) and application. Similar in suture lengths. Different in Predicate Device direction of barb (cog)configuration of barb (Cog) for LSCO Type, C-Cog Type and Forte Fix Type however no impact to form, fit, function, or safety of the suture. Substantially Equivalent
Needle Material	Stainless Steel Type 304L (cleared in K092831)	Stainless Steel Type 304L (cleared in K092831)	Identical Substantially Equivalent

VII. PERFORMANCE DATA

BIOCOMPATIBILITY

Per ISO 10993-1 the biological evaluation, testing and biological risk assessment have been completed and lead to the conclusion that the product meets form, fit, function and safety requirements for its intended use.

PERFORMANCE TESTING-BENCH

USP 43 - NF 38, Section <861> Sutures - Diameter
USP 43 - NF 38, Section <871> Sutures – Needle Attachment
USP 43 - NF 38, Section <881> Sutures - Tensile Strength
Suture Retention - Barb Holding Strength

Feeltech has completed the above stated testing services performed in accordance to applicable standard good practices and/or standards identified within this report. Testing has been completed as described herein. The decision rule applied is simple acceptance of the test results.

VIII. ANIMAL STUDIES (PERFORMANCE TESTING)

Animal studies were presented under an assessment of *In-vivo* biodegradation of absorbable V-Soft Line™ (PDO) suture in comparison with the predicate device Miracu™ Barbed Device (reference samples –predicate device) over time in Sprague-Dawley rat animal model system.

The study was carried out to evaluate the biodegradation of absorbable suture in Sprague-Dawley rats for a total of 12 weeks, after multiple 2 week interval examinations following necropsies. This study was performed in accordance with the USP 37 NF:2014 standards: absorbable surgical suture, tensile strength, sutures – diameter, and their acceptance criteria were met. Other parameters under investigation barb holding forces, residual tensile strength, and absorption (loss of mass) were demonstrated to reflect the biodegradation levels (indicators) over time were numerical determined.

No significant differences between all test groups and reference groups (predicate device) in all necropsy groups were evident. The V-Soft Line™ (PDO) suture performance was substantially equivalent to the predicate device.

IX. CLINICAL STUDIES (PERFORMANCE TESTING)

The V-Soft Line™ (PDO) Barbed Surgical Suture does not require clinical study. There are no clinical study requirements for this Class II product.

X. CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe and effective as the legal marketed predicate device.