October 20, 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: K251414
Trade/Device Name: Miracu™ Polydioxanone (PDO) Suture and Needle (MONO)
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable Polydioxanone Surgical Suture
Regulatory Class: Class II
Product Code: NEW
Dated: September 8, 2025
Received: September 8, 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
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K251414 |

Please provide the device trade name(s).

Miracu™ Polydioxanone (PDO) Suture and Needle (MONO)

Please provide your Indications for Use below.

The Miracu™ Absorbable Polydioxanone Suture with Needle (MONO) is 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K251414

# 510(k) Summary

Prepared on: 2025-10-20

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | Feeltech Co., Ltd. |
| Applicant Address | 4th Floor, Standard Factory5-dong, 1st Floor, Standard Factory1-dong, 3rd-4th Floors, Standard Factory2-dong 15, Jayumuyeok 2-gil Gunsan-si Jellabuk-do 54001 Korea, South |
| Applicant Contact Telephone | +82634686626 |
| Applicant Contact | Mr. Choi Cheol-Ho |
| Applicant Contact Email | yettos@empas.com |
| Correspondent Name | Albert Rego PhD, Inc (d.b.a Rego Associates) |
| Correspondent Address | 25401 Cabot Road, # 122 Laguna Hills CA 92653 United States |
| Correspondent Contact Telephone | (949) 632-8126 |
| Correspondent Contact | Dr. Albert Rego |
| Correspondent Contact Email | albert@regoassociates.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | Miracu™ Polydioxanone (PDO) Suture and Needle (MONO) |
| Common Name | Absorbable polydioxanone surgical suture |
| Classification Name | Suture, Surgical, Absorbable, Polydioxanone |
| Regulation Number | 878.4840 |
| Product Code(s) | NEW |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K181582 | DemeTECH DemeDIOX absorbable surgical suture | NEW |
| K212380 | PDS™ Plus Antibacterial Polydioxanone Synthetic Sterile Suture | NEW |
| K172602 | Miracu | NEW |
| K173779 | PDREX | NEW |

## Device Description Summary

21 CFR 807.92(a)(4)

Miracu™ synthetic absorbable PDO suture with needle is made of polydioxanone. The pigment for the violet dye is D&C Violet No.2. The

Miracu™ is available sterile after ethylene oxide (EO) gas sterilization and degrades or dissolves over time in tissue.

Each dyed (violet) suture has no barbs along the long axis of the suture monofilament with needle attachment. The Miracu™ Synthetic Absorbable PDO suture with needle (No Barb) approximates tissue is equivalent in form and function to the predicate device DemeDIOX (K181582).

The proposed suture is available in 4-0, 5-0, 6-0 suture sizes, which are the sizes identified in the currently recognized United States Pharmacopeia, and is equivalent to sizes available in the PDREX reference device (K173779).

The formation of barbs in the Miracu™ reduces the tensile strength relative to non-barbed suture material of the same size. Therefore, the suture tensile strength for the Non Barbed is not compromised and is equal or stronger than the barbed reference configuration. The Miracu™ non-barbed suture is made from the same material, sterilized in the same manner, and packaged as the barbed reference device Miracu™ (K172602).

The strength of the Miracu™ (non Barbed) can be compared with, and is substantially equivalent to, the publicly available information for the PDS Plus (K212380).

## Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The Miracu™ Absorbable Polydioxanone Suture with Needle (MONO) is 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.

## Indications for Use Comparison 21 CFR 807.92(a)(5)

The Indications for use are the same.

## Technological Comparison 21 CFR 807.92(a)(6)

The technological characteristics (i.e., design, material, chemical composition, principle of operation, energy source, etc.) are the same as in one or more of the predicate and/or reference device(s) identified above.

## Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The Miracu™ (Sterile Single use Polydioxanone Suture with Needle – common name used in the Bench Test Report) was subjected to performance and mechanical properties testing (absorbable sterilized suture in finished form) to determine if these devices conformed to the acceptance criteria. In addition, the verification of compliance to FDA recognized consensus standards, monographs and appropriate testing parameter sections are listed below of the currently FDA-recognized edition of the USP and ASTM.

Reference:
Guidance for Industry and FDA Staff - Surgical Sutures – Performance Criteria for Safety and Performance Based Pathway Document issued on April 11th, 2022.

The following standards (monographs) were utilized in the testing:

1) ASTM F1840-10(reapproved 2023, 2010 R23 Edition) Standard Terminology for Surgical Suture Needles
2) ASTM F1874-98 (Reapproved 2011) Standard Test Method for Bend Testing of Needles Used in Surgical sutures
3) ISO 7864:2016 Sterile hypodermic needles for single use
4) ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices
5) USP 37-NF32:2014 Monographs : Absorbable Surgical Suture
6) USP 43-NF38 <861> - diameter
7) USP 43-NF38 <871. Sutures – Needle Attachment
8) USP 43-NF38 <881> Sutures –Tensile Strength
9) ASTM D1683 - Seam Strength Testing

Miracu™ synthetic absorbable PDO suture with needle is made of polydioxanone. The pigment for the violet dye is D&C Violet No.2. The Miracu™ is available sterile after ethylene oxide (EO) gas sterilization and degrades or dissolves over time in tissue.

Each dyed (violet) suture has no barbs along the long axis of the suture monofilament with needle attachment. The Miracu™ Synthetic

Absorbable PDO suture with needle (No Barb) approximates tissue is equivalent in form and function to the predicate device DemeDIOX (K181582).

The proposed suture is available in 4-0, 5-0, 6-0 suture sizes, which are the sizes identified in the currently recognized United States Pharmacopeia, and is equivalent to sizes available in the PDREX reference device (K173779).

The formation of barbs in the Miracu™ reduces the tensile strength relative to non-barbed suture material of the same size. Therefore, the suture tensile strength for the Non Barbed is not compromised and is equal or stronger than the barbed reference configuration. The Miracu™ non-barbed suture is made from the same material, sterilized in the same manner, and packaged as the barbed reference device Miracu™ (K172602).

The strength of the Miracu™ (non Barbed) can be compared with, and is substantially equivalent to, the publicly available information for the PDS Plus (K212380).

The Miracu™ (Sterile Single use Polydioxanone Suture with Needle – common name used in the Bench Test Report) was subjected to performance and mechanical properties testing (absorbable sterilized suture in finished form) to determine if these devices conformed to the acceptance criteria. In addition, the verification of compliance to FDA recognized consensus standards, monographs and appropriate testing parameter sections are listed below of the currently FDA-recognized edition of the USP and ASTM.

Absorbtion testing (animal model) showed absorption comparable to superior to the reference device K212380, according to publicly available information. Retention of tensile strength varies based on the diameter (gauge) of the suture. An equivalent monifilament non-barbed suture, the Ethicon PDS™ Plus demonstrates that with smaller diameter sutures. For example, Feeltech's USP size 4-0 suture has a retained tensile strength of ca 81% after two weeks and ca 66% after four weeks, which is comparable to approximate strength retention of the smaller sizes for the Ethicon PDS™ Plus (K212380).

Reference:
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Surgical Sutures
Document issued on June 3, 2003

The following standards (monographs) were utilized in the testing:

1) USP 32:2009 Absorbable Surgical Suture
2) USP 37-NF 32: 2014 <881>Tensile Strength
3) USP 37-NF 32:2014 <861> Sutures - Diameter
4) USP 37-NF32:2014 <871> Sutures - Needle Attachment
5) USP 37-NF32:2014 Absorbable Surgical Suture
Needle Suturing Disposable Class 1 510(k) Exempt
6) ASTM F1840-10 (E2011) Standard Terminology for Surgical Suture Needles
7) ASTM F1874-98 9 Reapproved 2011) Standard Test Method for Bend Testing of Needles
Used in Surgical Sutures

No failed results were performed in any Miracu™ with the test results during the performing period, and Miracu™ satisfied all the acceptance criteria. Barb-related tests were not applicable to the devices in this submission.