November 14, 2018

Feeltech Co., Ltd.
% Dr. Albert Rego
Consultant
Albert Rego, Ph.D., Inc.
27001 La Paz Rd, #314
Mission Viejo, California 92691

Re: K172602
Trade/Device Name: Miracu
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable Polydioxanone Surgical Suture
Regulatory Class: Class II
Product Code: NEW
Dated: October 15, 2018
Received: October 17, 2018

Dear Dr. 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 (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); 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172602

Device Name
Miracu™ barbed surgical suture

Indications for Use *(Describe)*
The Miracu™ barbed surgical suture 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.

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.

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Tel: +82 63 468 6626 Fax:+82 63 468 6623

Feeltech (주) 필텍

510(k) Summary
(As required by 21 CFR 807.92)

I. **SUBMITTER:** Feeltech Co., Ltd.
3, 4 Floor, Standard Factory 2-Dong,
15, Jayumuyeok 2-gil, Gunsan-si, Jellabuk-do, 573-540 KOREA
Tel.: +82 63 468-6626
Fax: +82 63 468-6623

Contact Person: Jake Choi
Phone: +82 31 628-8560

Date Prepared: November 7, 2018

II. DEVICE:

Trade Name: Miracu™ (Miracu™ barbed surgical suture)

Common Name: Absorbable Polydioxanone Suture with Needle

Classification Name: Absorbable Polydioxanone Surgical Suture (21 CFR 878.4840) (NEW)

Regulatory Class: Class II

Classification Product Code: NEW

III. PREDICATE DEVICE:

510(k) Number: K133420
Product Name: TranQuill Barbed Device
Manufacturer: Surgical Specialties Corp.

IV. DEVICE DESCRIPTION:
Miracu™ synthetic barded surgical absorbable polydioxanone (PDO) suture with needle. The needle is straight, hollow, cannula and is pre-loaded onto the suture. 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 bi-directional barbs along the long axis of the suture monofilament. The Miracu™ Synthetic Absorbable PDO suture with needle approximate 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 suture is available in 4-0, 3-0, 2-0, and 0, suture sizes, which are the sizes identified in the currently recognized United States Pharmacopeia (USP).

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The Miracu™ is barbed to two sections on suture and the barbs on each section are opposite direction each other. The reason this suture has opposite barb direction is not to have type of movement described as sliding back and forth. Therefore, the effectiveness of suture for treatment is improved.
While the formation of barbs in the Miracu™ reduces the tensile strength relative to non-barbed suture material of the same size, tying of knots in non-barbed suture materials also reduce their effective strength. For this reason, the strength of the Miracu™ can be compared with USP knot strength of non-barbed suture as defined in the tale below.

TENSILE STRENGTH

Tensile Strength – USP criteria vs Actual (Barbed from USP Suture size)

USP Suture Size	USP Criteria (kgf)	Actual Suture Tensile Strength - barbed (kgf)	Actual Suture Tensile Strength - -barbed (N)	Miracu™ Tissue Device Equivalent Size
4-0	1.20	0.95	9.32	5-0
3-0	1.90	1.77	17.4	4-0
2-0	2.90	2.68	26.2	3-0
0	4.10	3.90	38.2	2-0
2	6.60	6.35	62.3	1

V. INDICATIONS FOR USE

The Miracu™ barbed surgical suture 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. TECHNOLOGICAL CHARACTERISTICS:

Miracu™ has the same fundamental scientific technology as the TransQuill Barbed Device Absorbable Surgical Suture, K133420.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The comparison of features and operation principles between Miracu™ from Feeltech Co. Ltd., and TranQuill Barbed Device (K133420) from Surgical Specialties Corp. is listed as follows:

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Category	Candidate Device Miracu™	Predicate Device TranQuill Barbed Device Absorbable Surgical Suture, K133420	Substantially Equivalent or Not Substantially Equivalent
Common Name	Suture Absorbable Synthetic Polydioxanone with Needle Suturing Disposable	Polydioxanone Absorbable Surgical Suture	Substantially Equivalent
Manufacturer	Feeltech Co., Ltd.	Surgical Specialties Corporation	Not Applicable
510(k) Number	K172602	K133420	Not Applicable
Indication for Use	The Miracu™ barbed surgical suture 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.	The TransQuill barbed device comprised of dyed PDO is indicated for use in soft tissue approximation where use of absorbable sutures is appropriate.	Indications for Use Similar with respect to usage on soft tissue approximation. Different in that the Miracu™ is specific to usage on the skin for dermatological applications, where the predicate is not restricted in the Indication for Use. Substantially Equivalent Design Similar in usage of suture type and application. Different in Interval between barbed sections from 10mm for Miracu™ and 25mm for the predicate. Substantially Equivalent
Sterile	E.O. Sterile	E.O. Sterile	Substantially Equivalent
Configuration	PDO Suture and Needle. The subject device is pre-loaded with a hollow needle and is not swaged.	PDO Suture and Needle. predicate suture being swaged to a standard suturing needle	Design Similar in usage of suture type and application. Different in Interval between barbed sections from 10mm (7 barbs per 10mm length) for Miracu™ and 25mm (16 barbs per 10mm length) for the predicate. Substantially Equivalent
Materials	Poly(1,4-dioxanone-2-one) 0.993g/g	Poly (dioxanone)	Substantially Equivalent

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Tel: +82 63 468 6626 Fax:+82 63 468 6623

Category	Candidate Device Miracu™	Predicate Device TranQuill Barbed Device Absorbable Surgical Suture, K133420	Substantially Equivalent or Not Substantially Equivalent
Color	Dyed suture (Violet) (0.025~0.075% w/w)	Dyed (violet)	Substantially Equivalent
Absorbable	Absorbable	Absorbable	Substantially Equivalent
Braid/Monofilament	Monofilament	Monofilament	Substantially Equivalent
Suture Size	4-0, 3-0, 2-0, & 0	4-0, 3-0, 2-0, 0, 1, & 2	Substantially Equivalent
Length of Suture[1]	90, 110, and 150 mm	140 mm (70 mm x 70 mm), 70 mm (35 mm x 35 mm), 280 mm (140 mm x 140 mm), 480 mm (240 mm x 240 mm), 200 mm (100 mm x 100 mm), 800 mm (400 mm x 400 mm), 600 mm (300 mm x 300 mm), 720 mm (360 mm x 360 mm), & 900 mm (450 mm x 45 mm)	Substantially Equivalent
Needle Material	Stainless Steel	Stainless Steel	Substantially Equivalent
Barb per the Linear Length of Suture	Barbed	Barbed	Substantially Equivalent
Barb angle	2~45°	2~45 °	Substantially Equivalent
Biocompatible	Yes	Yes	Substantially Equivalent

[1] Both the Subject and the Predicate devices have a barb configuration.

VIII. PERFORMANCE DATA

Laboratory testing regarding characteristics was performed on the Miracu™ to verify its safety and performance.

BIOCOMPATIBILITY

A biocompatibility assessment was performed on the patient contact materials of Miracu™ in accordance with ISO 10993-1:2009 standard. The test results generated from intracutaneous, acute systemic toxicity, cytotoxicity, bacteria reverse mutation study, implantation, subchronic, and sensitization, bacterial endotoxin - Limulus Amoebocyte Lysate (LAL) and material-mediated pyrogen (rabbit) tests supports assessment of biocompatibility for this medical device.

BENCH (PERFORMANCE TESTING)

MECHANICAL TESTING

Tests were performed in accordance with USP 37-NF 32:2014 dimension test, tensile strength, sutures, absorbable surgical suture, and ASTM F1874-98 9 reapproved 2011 standard test method for bend testing of needles used in surgical sutures. All the test results have met their respective acceptance criteria.

#3F, 4F, 15, Jayumuyeok2-gil, Gunsan-si, Jeollabuk-do, Korea
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ANIMAL STUDIES (PERFORMANCE TESTING)

Animal studies were presented under an assessment of *In-vivo* biodegradation of absorbable Miracu™ suture Miracu™ in comparison with the predicate device TranQuill 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 Miracu™ performance was substantially equivalent to the predicate device.

CLINICAL STUDIES (PERFORMANCE TESTING)

Clinical studies were not performed nor required.

IX. CONCLUSIONS

The device description, indications for use, technology, design of Miracu™ and the predicate device are similar, with the configuration differences described above. The performance testing data demonstrated substantial equivalence to the predicate device. This regulatory submission presents evidence and concludes this subject medical device, Miracu™ is substantially equivalent to the predicate device.