June 4, 2019

PDO MAX, Inc.
% Ms. Mary Vater
Regulatory Consultant
Medical Device Academy, Inc.
345 Lincoln Hill Rd.
Shrewsbury, Vermont 05738

Re: K190245
Trade/Device Name: PDS Barbed Suture, PDO MAXX Threads
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable Polydioxanone Surgical Suture
Regulatory Class: Class II
Product Code: NEW
Dated: March 6, 2019
Received: March 6, 2019

Dear Ms. Vater:

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/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 David Krause, Ph.D.
Acting Division Director
Division of Infection Control and Plastic Surgery Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190245

Device Name
PDO MAXX Threads Barbed Surgical Suture

Indications for Use *(Describe)*
The PDS Barbed Surgical Suture is indicated for use in soft tissue approximation where use of absorbable sutures 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

PDO Max, Inc.
4971 Bear Road
Liverpool, New York 13088
Tel: +1.315.708.9913

Contact Person: Giovanna McCarthy
Date Prepared: 4 February 2019

II. DEVICE

Name of Device: PDO MAXX Threads Barbed Suture
Classification Name: Suture, Surgical, Absorbable, Polydioxanone
Regulation: 21 CFR §878.4840
Regulatory Class: Class II
Product Classification Code: NEW

III. PREDICATE DEVICE

Predicate Manufacturer: Feeltech Co., Ltd.
Predicate Trade Name: Miracu
Predicate 510(k): K172602

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

PDO MAXX THREADS™ barbed sutures are made of polydioxanone (PDO) and have the colorant D&C Violet No. 2 (21 CFR 74.3602). The sutures are USP 0 suture in diameter and USP 2-0 suture in tensile strength, and 150 mm in length, swaged to a 19G/100 mm "L" Blunt needle and pre-loaded in a needle cannula. The sutures are inserted into the tissue using the cannula/needle. The barbed sutures have cut barbs along the axis of the monofilament that allows the suture to embed in the tissue after the surgeon has placed it; therefore, there is no need to tie a surgical knot. The sutures are absorbable in the body.

V. INDICATIONS FOR USE

The PDS Barbed Surgical Suture is indicated for use in soft tissue approximation where use of absorbable sutures 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 DEVCE

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

- Indications for Use – The predicate and subject device have almost indications for use; both are indicated for use in soft tissue approximation where use of absorbable sutures is appropriate,

specifically designed for use in the skin.

- Materials – The predicate and subject device materials are identical.
- Design – The predicate and subject device are equivalent in design. They are both made of the same basic monofilament with similar barbs cut into the monofilament. Both the predicate and subject devices are supplied to the user pre-loaded in a hollow needle.
- Energy Source – Neither the predicate nor the subject device requires an energy source.
- Performance Testing – Both the predicate and subject devices were subjected to the same biocompatibility and performance tests listed below.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Suture Biocompatibility Testing

- Cytotoxicity
- Irritation
- Acute Systemic
- Material Mediated Pyrogenicity
- Genotoxicity, Carcinogenicity, and Reproductive Test
- Endotoxin
- Sensitization

Needle Biocompatibility Testing

- Cytotoxicity
- Acute Systemic
- Material Mediated Pyrogenicity
- Intracutaneous Reactivity Test
- Skin Sensitization Test
- Hemolysis Test

Suture Performance Testing

- Suture Absorption
- Dimension Test
- Tensile Strength

Needle Performance Testing

- Inner/Outside Structure
- Dimension Test
- Elasticity Test
- Flexural Rigidity Test
- Draw Test
- Extraction Test

Electrical Safety and EMC Testing

Electrical safety and EMC testing were not applicable.

Animal Testing

- In Vivo Biodegradation in Sprague-Dawley Rat – Absorption and Tensile Strength over time

Clinical Testing

Clinical testing was not required to demonstrate the safety and effectiveness.

VIII. CONCLUSIONS

Based on a comparison of technological characteristics, indications for use, and performance data, it can be concluded that the proposed PDS Barbed Suture is substantially equivalent to the predicate device.