December 17, 2021

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

Re: K210871
Trade/Device Name: PDO Max Suture with Dual Needle
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable Polydioxanone Surgical Suture
Regulatory Class: Class II
Product Code: NEW
Dated: November 16, 2021
Received: November 16, 2021

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,

Deborah Fellhauer RN, BSN
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210871

Device Name
PDO Max Suture with Dual Needle

Indications for Use *(Describe)*
The PDO Max Suture with Dual Needle 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.

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510(k) SUMMARY

This 510(k) summary of substantial equivalence 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: +1.315.427.8229

Contact Person: Giovanna McCarthy
Date Prepared: December 8th, 2021

II. DEVICE

Name of Device: PDO Max Suture with Dual Needle
Classification Name: Suture, Surgical, Absorbable, Polydioxanone
Regulation: 21 CFR §878.4840
Regulatory Class: Class II
Product Classification Code: NEW

III. PREDICATE DEVICE

Predicate Device Manufacturer: Angiotech
Predicate Device Trade Name: Quill™ PDO Knotless Tissue-Closure Device (Polydioxanone)
Predicate Device 510(k): K120827

Reference Device Manufacturer: PDO MAX, Inc.
Reference Device Trade Name: PDS Barbed Suture, PDO MAXX Threads
Reference Device 510(k): K190245

IV. DEVICE DESCRIPTION

The synthetic barbed Sutures are made of polydioxanone (PDO) with needles attached to each end of the suture. The needles are straight and pre-loaded onto each end of the suture filament. The pigment for the violet dye is D&C Violet No.2. The sutures are inserted into the tissue using the needles. Each dyed (violet) suture has bi-directional barbs along the long axis of the suture monofilament. The suture is barbed into two sections and each section are in opposite direction. The device is available sterile after ethylene oxide (EO) gas sterilization and degrades or dissolves over time in tissue.

The Synthetic Absorbable 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 2-0, 0 and 1, suture sizes, which are the sizes identified in the currently recognized United States Pharmacopeia (USP). The needles are 50mm in length (each) and are reverse cutting type.

V. PRINCIPLES OF OPERATION

The PDO Max Suture with Dual Needle has the needles pre-attached to each end of the suture. The needle on one end is inserted into the desired tissue location and pushed through to exit the tissue with the suture following behind. Suture is pulled through until the transition point (non-barbed, middle section) has

reached the tissue. Estimation of the center of the device can be aided by taking a single bite of tissue, then aligning the two needles until both ends of the suture are roughly equal in length. Techniques for soft-tissue approximation may vary depending on type of tissue and closure. Once soft tissue is approximated, the surgeon ensures that the barbed section of the suture is present where the tissue approximation is desired. The excess suture length is trimmed and the needle and extra suture length are removed. Each suture has bi-directional 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.

VI. INDICATIONS FOR USE

The PDO Max Suture with Dual Needle 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 similar indications for use; both are indicated for use in soft tissue approximation where use of absorbable sutures is appropriate.
- Materials – The predicate and subject device are both made of polydioxanone (PDO) sutures and medical grade stainless steel needles.
- 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 with attached needles on each end, and have bi-directional barbs.
- Performance Testing – The predicate and subject device were subjected to performance testing under the NEW product code, including in vivo animal studies to support substantial equivalence in terms of performance.

The table below provides comparison of key features of the subject and predicate devices.

Key Feature	**PDO Max Suture with Dual Needle**	**Predicate Device (K120827)**
Suture Material	Same as predicate	Polydioxanone (PDO)
Suture Color	Same as predicate	Violet
Suture Length	200mm (USP 2-0, 0 and 1)	200mm (USP 2-0) 205mm (USP 0) 215mm (USP 1) *Other USP diameter sizes included in the range of 2 to 4-0.*
Needle Material	Same as predicate	Stainless steel (medical grade)
Barb Design	Same as predicate	Bi-directional with transition point in the middle
USP Sizes	Three available sizes (USP 2-0 to 1). These sizes are encompassed within the available sizes for the predicate device.	Variety of sizes (USP 2 to 4-0)
Needle Length	50mm (Same as predicate)	According to Quill's online catalog, they offer a variety of needle lengths and types. However, the needles for sutures

		USP sizes 2-0, 0 and 1 are available in 50mm lengths (as indicated in the publicly available online catalog).
Needle Type	Same as predicate	Straight
Needle Attachment	Same as predicate	Needles are pre-attached to each end of the suture.

Moreover, the previously cleared PDO Max suture (K190245) is cited in this submission as a reference device. The subject device and the reference device are identical in material and manufacturing process. The design of the sutures is also similar, as they both have cut barbs and are bi-directional. The main difference in design between the reference and subject devices is the barb pattern. Nonetheless, PDO Max has proposed to leverage performance data from K190245 in order to support this submission. Although there are some differences in barb design between both devices, these do not impact any of the leveraged testing data.

VII. PERFORMANCE DATA

The following performance testing has been conducted (or leveraged from K190245) to support determination of substantial equivalence of the subject device. This includes biocompatibility testing of the suture component, biocompatibility testing of the needle component, sterilization validation, shelf-life study, USP suture and needle performance testing (as required under the NEW product code for absorbable polydioxanone sutures) and in vivo animal testing.

Suture Biocompatibility Testing (leveraged from K190245)

- Cytotoxicity
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Intracutaneous Reactivity Test
- Skin Sensitization Test
- Genotoxicity
- Implantation Test

Needle Biocompatibility Testing

- Cytotoxicity
- Sensitization
- Intracutaneous Irritation
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity

Sterilization Validation (leveraged from K190245)

- EO Sterilization Validation in accordance with ISO 11135:2014
- ucm109897 – Sterilization Guidance

Shelf-Life Study (leveraged from K190245)

- Accelerated Aging

Suture Performance Testing

- Suture Absorption
- Dimension Test

- Tensile Strength

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Needle Performance Testing

- Dimension Test
- Flexural Rigidity Test
- Pierce Test
- Corrosion resistance
- Needle Attachment Test

Animal Testing (leveraged from K190245)
In Vivo Biodegradation in Sprague-Dawley Rat – Absorption and Tensile Strength over time

Barb Holding Strength Testing
A barb holding strength test was conducted to compare the barb holding strength of the subject device against the predicate device. Suture samples were inserted in porcine tissue to represent skin tissue. Test results demonstrated that the barb holding strength of the subject device sutures is non-inferior to the predicate device.

Clinical Testing
Clinical testing was not required to support substantial equivalence.

VIII. CONCLUSIONS

The subject device has similar indications for use to the predicate device. Moreover, both devices also have similar technological characteristics such as barb design and materials of manufacture. Appropriate performance testing was conducted (or leveraged from K190245) to support determination of substantial equivalence of the subject device. The results of this testing demonstrates that the PDO Max Suture with Dual Needle is substantially equivalent in safety and performance to the predicate device.