June 12, 2026

Sutura Medical Technology, Inc.
Annie Kim
Regulatory Affairs Manager
3 Allied Drive, Suite 210
Dedham, Massachusetts 02026

Re: K252171
Trade/Device Name: Barbed PDO Suture
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable Polydioxanone Surgical Suture
Regulatory Class: Class II
Product Code: NEW
Dated: May 8, 2026
Received: May 11, 2026

Dear Annie Kim:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.
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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)*
K252171

Device Name
Barbed PDO Suture

Indications for Use *(Describe)*
The Barbed PDO Suture is indicated for placement in the subcutaneous plane for temporary fixation of the cheek adipose layer in midface suspension surgery.

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.

510(k) #: K252171	**510(k) Summary**	Prepared on: 2026-0605

Contact Details

Applicant Name	Sutura Medical Technology Inc.
Applicant Address	2121 SW 3rd Avenue, Suite 500 Miami FL 33129 United States
Applicant Contact Telephone	(570) 550-0700
Applicant Contact	Ms. Annie Kim
Applicant Contact Email	akim@healthpolicyassociates.com

Device Name

Device Trade Name	Barbed PDO Suture
Common Name	Barbed PDO Suture
Classification Name	Suture, surgical, absorbable, polydioxanone
Regulation Number	21 CFR 878.4840
Product Code	NEW

Legally Marketed Predicate Devices

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K192423	Mint Product Family	NEW
K191361	DemeDIOX Barbed Absorbable Surgical Suture	NEW

Device Description Summary

The Barbed PDO Suture is an absorbable, sterile surgical monofilament suture composed of polyester, poly (p-dioxanone). The Barbed PDO Suture consists of an absorbable monofilament strand thread with spiral bidirectional barbs and is supplied pre-loaded with a

cannula, available in suture size USP 5-0 to 2. The material is dyed with D&C Violet No.2. and contains no additives. The barbing allows for tissue approximation without the use of surgical knots.

The mechanism of action is based on tissue fixation in an elevated position. The device consists of an absorbable PDO monofilament with bidirectional barbs. When placed in the subcutaneous plane, the barbs engage surrounding soft tissue, allowing the suture to anchor and maintain tissue in a repositioned (elevated) state.

Intended Use/Indications for Use

The Barbed PDO Suture is indicated for placement in the subcutaneous plane for temporary fixation of the cheek adipose layer in midface suspension surgery.

Indications for Use Comparison

The subject and predicate device (Mint Product Family, K192423) share the same intended use of temporary fixation and suspension of facial soft tissue in an elevated position. Both devices are intended for subcutaneous placement to elevate and support cheek tissue, and therefore operate within the same intended use and mechanism of action.

Technological Comparison

The subject device and the predicate device (Mint Product Family, K192423) have shared technological characteristics, including: synthetic absorbable monofilament PDO suture material, bi-directional barbs along the length of the suture, implantable use with long-term (>30 days) tissue contact, ethylene oxide sterilization, and the same principle of action. Differences in technique of deployment and suture size range do not alter the fundamental mechanism of action or intended use. The cannula-based delivery method represents an alternative, well-established technique for subcutaneous placement in aesthetic procedures as it may reduce the risks of puncturing blood vessels and nerves as it travels beneath the skin. Additionally, the subject device is consistent with the reference device, DemeDIOX Barbed Absorbable Surgical Suture (K191361), in terms of available size range. Neither of these differences raise new questions of safety and effectiveness.

Characteristics	**Subject Device** **Sutura Barbed PDO Suture**	**Predicate Device** **Mint Product Family (K192423)**	**Reference Device** **DemeDIOX Barbed Absorbable Surgical Suture (K191361)**	**Comparison**
FDA Classification	Class II	Class II	Class II	Same
Product Code	NEW	NEW	NEW	Same
Regulation Number	21 CFR 878.4840	21 CFR 878.4840	21 CFR 878.4840	Same

Regulation Name	Suture, Surgical, Absorbable, Polydioxanone	Suture, Surgical, Absorbable, Polydioxanone	Suture, Surgical, Absorbable, Polydioxanone	Same
Indication for Use	The Barbed PDO Suture is indicated for placement in the subcutaneous plane for temporary fixation of the cheek adipose layer in midface suspension surgery.	Indicated for use in mid-face suspension surgery to temporarily fixate the cheek subcutaneous fat layer and SMAS layer in an elevated position for the treatment of moderate to severe nasolabial folds.	Indicated for use in soft tissue approximation where use of absorbable sutures is appropriate.	The subject device's indication for use is similar to that of the predicate device in that they both intend to temporarily fixate and elevate the cheek sub dermis. The reference device's indication is broader, as it is intended for general soft tissue approximation.
Material Composition	Polydioxanone (PDO) suture; Stainless steel (STS-304)	Polydioxanone (PDO) suture; Stainless steel (SUS 304)	Polydioxanone (PDO) suture; Stainless steel (STS-304)	The subject and predicate devices utilize the same PDO suture material and equivalent stainless steel materials (STS-304 and SUS-304), which are recognized designations for Type 304 stainless steel. No differences that would impact safety or performance.
Suture Characteristic	Synthetic Absorbable Monofilament	Synthetic Absorbable Monofilament	Synthetic Absorbable Monofilament	Same
Technique of Deployment	Cannula	Needle	Needle	Different; both are established techniques for subcutaneous placement in aesthetic procedures and enable accurate positioning of the suture within the intended tissue plane. This difference does not alter the fundamental mechanism of action or intended use and does not raise new questions

				of safety or effectiveness.
Technological Characteristics	Bi-directional barbs along the long axis of the suture monofilament	Bi-directional barbs along the long axis of the suture monofilament	Uni-directional barbs along the long axis of the suture monofilament	Same as predicate device
Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Same
Absorbable	Absorbable	Absorbable	Absorbable	Same
Size (USP)	Available in sizes 5-0 to 2.	Size 1-0	Available in sizes 5-0 to 2.	Different from predicate device; Same as reference device
Patient Contact	Implant	Implant	Implant	Same
Duration of Contact	Over 30 Days	Over 30 Days	Over 30 Days	Same

Non-Clinical and/or Clinical Tests Summary & Conclusions

In accordance with the Class II Special Controls Guidance: Surgical Sutures; Guidance for Industry and FDA (June 2003), the Barbed PDO Suture was evaluated through nonclinical testing and supporting information to demonstrate safety and performance. These evaluations included conformity to applicable USP standards (USP <861> Suture Diameter and USP <881> Tensile Strength), sterility and bacterial endotoxin testing, shelf life supported by stability testing, biocompatibility assessment, and performance testing, including barb holding strength (pull-out testing).

A prospective, multi-center clinical study was conducted to evaluate the safety and effectiveness of the Barbed PDO Suture for midface suspension surgery. A total of 57 subjects were enrolled across four U.S. sites, with 48 subjects completing the study. The safety profile observed in the clinical study was consistent with that expected for suture-based procedures. No serious adverse events or unanticipated adverse device effects were reported. Most adverse events were mild in severity and resolved without sequelae.

Based on the totality of nonclinical and clinical evidence, the Barbed PDO Suture is safe and effective for its intended use and performs as well as the identified legally marketed predicate device.