June 03, 2026

Tas Medical, Inc.
% Maureen O'Connell
Regulatory Consultant
Oconnell Regulatory Consultants, Inc.
44 Oak St.
Stoneham, Massachusetts 02180

Re: K261484
Trade/Device Name: Tissue Approximation System
Regulation Number: 21 CFR 878.5020
Regulation Name: Nonabsorbable Polyamide Surgical Suture
Regulatory Class: Class II
Product Code: GAR
Dated: May 5, 2026
Received: May 5, 2026

Dear Maureen O'Connell:

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.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive Surgery Devices
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Infection Control Devices
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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)*
K261484

Device Name
Tissue Approximation System

Indications for Use *(Describe)*
The Tissue Approximation System (TAS) is indicated for use in soft tissue approximation, including use in general surgery procedures such as minimally invasive ventral hernia and abdominal wall closure less than 10cm, but not for use in ophthalmic, neurologic, or cardiovascular procedures.

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.

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510(k) SUMMARY
K261484

Sponsor
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Official Correspondent
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Stoneham, MA 02180
Phone: 978-207-1245

Date Prepared: June 2, 2026

Trade Name of Device
Tissue Approximation System (TAS)

Common or Usual Name
Suture

Classification Name
Suture, Nonabsorbable, Synthetic, Polyamide
21 C.F.R. §878.5020
Class II
Product Code: GAR

Predicate Device
TAS Medical, Inc. Tissue Approximation System cleared in K220980

Device Description
The Tissue Approximation System (TAS) consists of a polyamide (nylon) "zip-tie" attached to a braided polyethylene terephthalate (PET, or Dacron) leader to aid insertion. A one-way clasp allows for fixation of the tissue approximation without the need to tie surgical knots.

When packaged for commercial distribution, four zip-ties with integrated suture leaders are accompanied by hand-held instruments that can be optionally used for insertion.
The kits are provided sterile within a polyethylene/foil pouch.

Indications for Use
The Tissue Approximation System (TAS) is indicated for use in soft tissue approximation, including use in general surgery procedures such as minimally invasive ventral hernia and abdominal wall closure less than 10cm, but not for use in ophthalmic, neurologic, or cardiovascular procedures.

Summary of Technological Characteristics Compared to Predicate Device
The Tissue Approximation System described in this notification and for use under the conditions of the proposed labeling is substantially equivalent to the Tissue Approximation System predicate device cleared in K220980.

The Tissue Approximation System that is the subject of this Special 510(k) is the same as the device cleared in K220980 with the exception of:

- Modification of the materials used in the packaging from Multi-layer Tyvek-Nylon/LDPE film to Multi-layer Foil Nylon/LDPE film
- Introduction of two new kit models in addition to the T-4000 kit cleared in K220980. Kit model T-LAP is identical to the T-4000 kit except it does not include a suture leader loop. Kit model T-5000 includes the identical zip-ties as the T-LAP kit but fewer hand-held instruments.

Performance Data
Verification and validation testing was completed and passed for the Tissue Approximation System with 12-month shelf life. A shelf-life of 12 months was validated using accelerated aging for the devices, packaging, and the sterile barrier. Testing based on the USP Monographs (including <881, Tensile Strength> and <871, Sutures - Needle Attachment>) showed that the TAS has a strength that meets or exceeds the requirement of USP Size 7, and the secured TAS zip-tie is as secure as the predicate device tied in a standard square knot.

Sterilization processes were validated per ISO 11137, and sterility was validated to SAL 10^{-6} with a sterilization dose of 25 kGy by the validation method VDmax^{25}.

Performance data supports substantial equivalence with the Tissue Approximation System cleared in K220980 as the same test methods were utilized and all testing was passed.

Conclusion
The Tissue Approximation System described in this notification and for use under the conditions of the proposed labeling is substantially equivalent to a legally marketed predicate device that is Class II medical device, the Tissue Approximation System cleared in K220980.