July 5, 2023

TAS Medical, Inc.
℅ Maureen O'connell
President
O'Connell Regulatory Consultants, Inc.
44 Oak Street
Stoneham, Massachusetts 02180

Re: K220980
Trade/Device Name: Tissue Approximation System (TAS)
Regulation Number: 21 CFR 878.5020
Regulation Name: Nonabsorbable Polyamide Surgical Suture
Regulatory Class: Class II
Product Code: GAR
Dated: March 8, 2023
Received: March 9, 2023

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 (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,

David Krause -S

David Krause, Ph.D.
Deputy Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220980

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.

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510(k) SUMMARY

TAS Medical, Inc.
Tissue Approximation System (TAS)

510(k) Owner
TAS Medical
1100 Industrial Road, Suite 16
San Carlos, CA 94070

Submission Correspondent
Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
44 Oak Street
Stoneham, MA 02180
Phone: 978-207-1245

Date Prepared: June 28, 2023

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
Sutumed Sutulon Suture cleared in K123034

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 kit will be provided sterile within a polyethylene/Tyvek 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.

Substantial Equivalence
The predicate device for TAS is the Sutumed Sutulon Suture cleared in K123034. Both devices are intended for use in soft tissue approximation and are prescription devices for use by trained healthcare providers. The TAS zip-tie shares important technological characteristics with the predicate device (both are non-absorbable nylon monofilament sutures), however, there are also some differences, such as the zip-tie having a rectangular cross-section, not a USP diameter, and the zip-tie using a clasp rather than a knot. The technological differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and the differences do not affect the safety and effectiveness of the device when used as labeled. Regarding fixation, the predicate device uses knots to maintain the tension set by the user. The subject device is maintained by the zip-tie's clasp. Both devices maintain the tension set by the user, thus they are substantially equivalent. Regarding cross-sectional shape, the primary function of the devices is to approximate soft tissue, which is not affected by cross-sectional shape. Both of these technological characteristic differences, as well as overall designs, were evaluated through performance testing, which demonstrated substantial equivalence.

Performance Data
Performance data included a large animal, GLP compliant study comparing the closure of full thickness, midline abdominal wall incisions comparing TAS (Test Article) to the predicate device (Control Article) used as labeled (e.g., fixation methods, no surgical mesh). Study endpoints included comparable incision healing, absence of device-associated serious non-transient tissue swelling, necrosis, dehiscence, hematoma, or extrusion in the Test Article as compared to the Control Article. All predefined safety and effectiveness endpoints were met, demonstrating that the different technological characteristics do not affect the safety/effectiveness when used as labeled.

Biocompatibility testing was conducted for the TAS per ISO 10993 and demonstrated substantially equivalent safety. 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 $VD_{max}25$. Individual device testing was conducted to demonstrate the ability of each device to perform its function. A shelf-life of 12 months was validated using accelerated aging for the devices, packaging, and the sterile barrier. All of the verification and validation testing was completed and passed for the Tissue Approximation System with 12-month shelf life.

Human factors validation testing was conducted which demonstrated that the device could be used by the intended users and under the expected use conditions without errors that could result in serious harm.

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, the length of the TAS zip-tie is no less than 95.0% of the length stated on the label and the secured TAS zip-tie is as secure or better than the predicate device tied in a standard square knot.

Therefore, the Tissue Approximation System is substantially equivalent to the predicate device.