March 12, 2020

Applied Medical Technology, Inc.
Joy Tubero
Regulatory Affairs Specialist
8006 Katherine Blvd.
Brecksville, Ohio 44141

Re: K193612
Trade/Device Name: AMT Suture Delivery System
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: Class II
Product Code: KGC
Dated: December 20, 2019
Received: December 26, 2019

Dear Joy Tubero:

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,

Shanil P. Haugen, Ph.D.
Acting Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K193612

Device Name
AMT Suture Delivery System

Indications for Use *(Describe)*
The AMT Suture Delivery System is intended for anchoring the wall of a hollow viscus to the abdominal wall prior to the introduction of interventional catheters and stay in place for up to 14 days in child, adolescent, and adult populations.

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.

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"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."

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510(k) Summary

AMT Suture Delivery System

I. SUBMITTER:

Applied Medical Technology, Inc.
8006 Katherine Boulevard
Brecksville, OH 44141
Phone: 440-717-4000
Fax: 440-717-4200

Contact Person: Joy Tubero – Regulatory Specialist
Email: joy.tubero@appliedmedical.net
Date Prepared: February 19, 2020

II. DEVICE INFORMATION:

Trade/Device Name: AMT Suture Delivery System
Common Name: Gastrointestinal tube and accessories
Classification Name: Gastrointestinal tube and accessories (21 CFR 876.5980)
Product Code: KGC
Regulatory Class: Class II

III. PREDICATE INFORMATION:

Predicate Device: K182832, Enterostomy Suture Anchor Set (Cook, Inc.; cleared on June 26, 2019).

****This predicate devices has not been subject to design-related recalls.**

IV. INDICATIONS FOR USE:

The AMT Suture Delivery System is intended for anchoring the wall of a hollow viscus to the abdominal wall prior to the introduction of interventional catheters and stay in place for up to 14 days in child, adolescent, and adult populations.

V. DEVICE DESCRIPTION:

The Suture Delivery System is a sterile, single use suturing device designed to pass suture percutaneously through tissues in order to anchor the wall of a hollow viscus to the abdominal wall prior to the introduction of interventional catheters. The non-absorbable suture meets requirements established by the United Stated Pharmacopeia (USP) for non-absorbable surgical suture. The suture is provided pre-loaded in a hand-held, manually operated, disposable suture application device. Only the suture and the anti-splay component are intended to remain in place while the wall of the viscous adheres to the abdominal wall; all other components of the delivery system are removed completely and discarded.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE:

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TABLE 5.1- TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT DEVICE AND THE PREDICATE DEVICES		
	Subject Device:	**Predicate:**
Device Class and Product Code:	Class II; KGC	Class II; KGC
	Substantial Equivalence:	Same
Sterilization:	Sterile (Ethylene Oxide), single use only. Sterility Assurance Level (SAL) 10^{-6}	Sterile (Ethylene Oxide), single use only. Sterility Assurance Level (SAL) 10^{-6}
	Substantial Equivalence:	Same
Prescription	Single use: Prescription Only.	Single use: Prescription Only.
	Substantial Equivalence:	Same
Indications for Use:	The AMT Suture Delivery System is intended for anchoring the wall of a hollow viscus to the abdominal wall prior to the introduction of interventional catheters and stay in place for up to 14 days in child, adolescent, and adult populations.	The Enterostomy Suture Anchor Set is intended for anchoring the wall of a hollow viscus to the abdominal wall prior to the introduction of interventional catheters and stay in place for up to 14 days in child, adolescent, and adult populations.
	Substantial Equivalence:	Similar
Intended Use:	Approximation of the wall of a hollow viscus to the anterior abdominal wall prior to the introduction of interventional catheters.	Approximation of the wall of a hollow viscus to the anterior abdominal wall prior to the introduction of interventional catheters.
	Substantial Equivalence:	Same
Principles of Operation	•Needles inserted percutaneously through the abdominal wall and into a hollow viscus. •Securement achieved by manual (non-powered) activation of application device. •Needles are removed, leaving behind suture. •Anchoring achieved by tension applied to the suture.	•Needle inserted percutaneously through the abdominal wall and into a hollow viscus. •Securement achieved by manual (non-powered) activation of application device. •Needle is removed, leaving behind sutures and metal anchors. •Anchoring achieved by tension applied to the sutures.
	Substantial Equivalence:	Similar

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TABLE 5.1- TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT DEVICE AND THE PREDICATE DEVICES		
	Subject Device:	**Predicate:**
Major Design Characteristics	• Device is preloaded with non-absorbable suture. • Insert needles to percutaneously deliver suture. • All suture securement. • Stainless steel and plastic construction.	• Device is preloaded with non-absorbable sutures and anchors. • Insert needle to percutaneously deliver suture and anchor. • Suture and metal anchor securement. • Stainless steel and plastic construction.
	Substantial Equivalence:	Similar

As outlined above, minor differences exist among the AMT Suture Delivery System and the predicate devices. These differences include:

- Material of Retention: The subject device applies tension to approximate tissues using only suture material. The predicate device approximates tissues using suture attached to internal metal anchors.
- Method of deployment: The subject device features a delivery system featuring two needles that when deployed, pass suture from one needle to the other in order to form a percutaneous u-stitch; the predicate uses a single needle that when deployed percutaneously delivers suture and metal anchors.

These design differences between the Suture Delivery System (subject device), and the predicate (K182832) do not raise different questions of safety and/or effectiveness from the predicate device. The intended use and indications for use remain the identical between the AMT Suture Delivery System and the predicate device.

VII. PERFORMANCE DATA:

A. Biocompatibility Testing:

Following a well-documented biological evaluation plan, biocompatibility testing results demonstrate that the device is in compliance with ISO 10993-1- Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing.

- ISO 10993-1 Biological Evaluation of Medical Devices
  – Part 1: Evaluation and testing within a risk management process
- ISO 10993-5 Biological Evaluation of Medical Devices
  – Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10 Biological Evaluation of Medical Devices
  – Part 10: Tests for irritation and skin sensitization.
- ISO 10993-11 Biological Evaluation of Medical Devices
  – Part 11: Tests for systemic toxicity
- ISO 10993-12 Biological Evaluation of Medical Devices

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– Part 12: Sample preparation and reference materials

- ISO 10993-17 Biological Evaluation of Medical Device
  – Part 17: Toxicological risk assessment of medical device constituents
- USP <151> Pyrogen Test (USP Rabbit Test)

B. Software:

There are no software components related in any way to this device. Therefore, this section for Software Validation is not applicable to this device.

C. Electromagnetic Compatibility & Electrical Safety:

The metal suture delivery component is discarded after placing suture in the patient's tissues. Use of the manually operated suture delivery device leaves only a suture in the patient. Therefore, Electromagnetic Compatibility and Electrical Safety Validation is not applicable to this device.

D. Performance Testing:

AMT conducted various performance tests on the components contained within the AMT Suture Delivery System. Testing found that all components and materials met or exceeded design specifications established by AMT.

1. Sterilization

The Micro Transgastric Feeding Device is provided sterile (ethylene oxide) and testing has been completed to evaluate the sterilization process. The tests carried out are outlined below:

- Testing per ANSI/AAMI/ISO 11135:
  - Sterilization process validation
- Testing per ISO 10993-7:
  - Part 7: Ethylene Oxide Sterilization Residuals.
- Bacterial Endotoxin Testing:
  - USP chromogenic method

The subject device is ethylene oxide sterilized, and has been validated to confirm a Sterility Assurance Level (SAL) of 10^{-6}. The sterilization processing complies with the standards.

2. Shelf Life

The sterilized packaging for the subject device was tested in accordance with the following:

- Testing in accordance with ASTM F1980-16:
  - Accelerated aging of sterile barrier systems
- Testing per ISO 11607:
  - Packaging system performance testing

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- Testing per ISTA 3A:
  - Packaged products for parcel delivery system shipments

Testing of the sterile barrier system has indicated that the packaging for the subject device complies with the standards.

3. Bench Testing

Bench tests have been carried out to demonstrate conformance to applicable recognized standards and to assure reliable design and performance under the specified testing parameters according to predetermined criteria. The tests carried out are outlined below:

- Testing per AMT specifications:
  - Deployment force
  - Tensile testing
- Testing per ISO 7864:
  - Needle hub bond
  - Needle Penetration
- Testing per USP <871>:
  - Suture Bond
- Testing per USP <881>:
  - Suture Tear Strength
- Testing per ISO 9626:
  - Resistance to Breakage (Needle)
  - Needle Stiffness

The AMT Suture Delivery System met or exceeded all the acceptance criteria and does not raise new questions of safety or effectiveness.

E. Animal Study: Animal testing was NOT performed.

F. Clinical Study: Clinical testing was NOT performed.

VIII. CONCLUSION:

The AMT Suture Delivery System can be found substantially equivalent to the predicate device cleared under K182832 in intended use, performance, and principles of operation. The minor design differences between the subject and the legally marketed predicate do not raise different questions of safety and/or efficacy, and the information submitted in the application demonstrates that the subject device is at least as safe and effective as the current legally marketed device.