July 5, 2024

Applied Medical Technology, Inc.
Jennifer Hazou
Regulatory Affairs Specialist
8006 Katherine Blvd.
Brecksville, Ohio 44141

Re: K241111
Trade/Device Name: AMT Suture Passer
Regulation Number: 21 CFR 21 CFR 876.1500
Regulation Name: Laparoscope, General & Plastic Surgery
Regulatory Class: Class II
Product Code: GCJ
Dated: April 22, 2024
Received: April 22, 2024

Dear Jennifer Hazou:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.07.05 10:56:26 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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.

Submission Number *(if known)*

K241111

Device Name

AMT Suture Passer

Indications for Use *(Describe)*

The AMT Suture Passer is indicated to pass suture through soft tissues of the body during endoscopic/laparoscopic surgery and interventional radiology procedures 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.

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510(k) Summary

AMT Suture Passer

I. SUBMITTER:

Applied Medical Technology, Inc.
8006 Katherine Boulevard
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Phone: 440-717-4000
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Contact Person: Jennifer Hazou – Regulatory Affairs Specialist
Email: Jennifer.Hazou@appliedmedical.net
Date Prepared: June 25, 2024

II. DEVICE INFORMATION:

Trade/Device Name: AMT Suture Passer
Common Name: Laparoscope, General & Plastic Surgery
Regulation Number: 21 CFR 876.1500
Regulation Name: Laparoscope, General & Plastic Surgery
Regulatory Class: II
Product Code: GCJ

III. PREDICATE INFORMATION:

Carter-Thomason Predicate: K980123 (Needle Point Suture Passer Instrument Set - CTSG; Carter-Thomason)

AMT Predicate Device: K193612 (Suture Delivery System; Applied Medical Technology, Inc.)

Teleflex Predicate Device: K192490 (Cottony II Polyester Suture; Teleflex Medical)

Cook Predicate Device: K182832 (Cope Pediatric Gastrointestinal Suture Anchor Set & Enterostomy Suture Anchor Set; Cook Incorporated)

**** The predicate devices have <u>not</u> been subject to design-related recalls.**

IV. INDICATIONS FOR USE:

The AMT Suture Passer is indicated to pass suture through soft tissues of the body during endoscopic/laparoscopic surgery and interventional radiology procedures in child, adolescent and adult populations.

V. DEVICE DESCRIPTION:

The AMT Suture Passer is a sterile, single-case use, hand-held suture grasping device. The device features a hypodermic needle through which a suture can be passed and retrieved through another. The retrieval component may be offered in two configurations: a non-magnetic version, and a

magnetically assisted version, using a grasper with a magnetized arm. Using either configuration, the AMT Suture Passer provides more flexibility in stitch geometry and approach than traditional U-stitches. The preferred method to introduce the suture is through a separate introducer needle; the AMT Suture Passer Kit with Magnet Assist instrument set bundles the magnetically assisted configuration of the AMT Suture Passer with an introducer needle and two magnetic sutures to create a non-procedure-specific kit.

For the magnetically assisted configuration, the magnetized arm of the grasper works in conjunction with a magnetic suture to reduce the technical difficulty of intracorporeal suture retrieval under laparoscopic, endoscopic, radiologic, or ultrasound guidance. This magnet-assist technology is derived from the ATLAS Suture Delivery System (K193612), also manufactured by Applied Medical Technology, which performs the same clinical function and is used in similar clinical applications.

Both configurations of the AMT Suture Passer feature identical components, except for the end-effectors, and make use of Luer-lock compatible hubs that allow a syringe to be attached for the purpose of administering contrast through the device. The contrast enters through the Luer hub and exits from the distal end of the needle, which allows the needle position to be verified prior to passing the suture during interventional radiology procedures.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATES:

		Subject	Carter-Thomason Predicate	AMT Predicate	Cottony Predicate	Cope Predicate	Comparison
		AMT Suture Passer (KXXXXXX)	Carter-Thomason SG Suture Passer (K980123)	ATLAS Suture Delivery System (K193612)	Cottony II Suture (K153076, K021019, K192490)	Cope Enterostomy Suture Anchor Set and Cope Pediatric Gastrointestinal Suture Anchor Set (K182832)	
Classification	**Device Classification**	Class II	Class II	Class II	Class II	Class II	SAME AS PREDICATE The subject device has the same classification and product code as the predicate.
	Product Codes	GCJ	GCJ	KGC	GAT	KGC	
	Regulation No.	876.1500	876.1500	876.5980	878.5000	876.5980	
	Panel	General & Plastic Surgery	General & Plastic Surgery	Gastroenterology/ Urology	General & Plastic Surgery	Gastroenterology/ Urology	
Sterility	**Condition**	Provided sterile	Provided sterile	Provided sterile	Provided sterile	Provided sterile	SAME AS PREDICATE The subject device and predicate devices are sterile, single-use devices that are not re-processable. Sterilization method (EO) is the same and similar packaging is employed, including a tray for organization, and a peel-open Tyvek lid to maintain the sterile barrier. The subject device also uses a pouch, which provides a second sterile barrier.
	Reprocessing	Single use only; not re-processable	Single use only; not re-processable	Single use only; not re-processable	Single use only; not re-processable	Single use only; not re-processable	
	Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	
	Packaging	Tray w/peel-open Tyvek lid inside peel-open Tyvek pouch	Tray w/ peel-open Tyvek lid	Tray w/peel-open Tyvek lid inside peel-open Tyvek pouch	Peel-open paper packet inside peel-open Tyvek pouch	Peel-open Tyvek Pouch	
	Assurance Level	SAL 10^{-6}	SAL 10^{-6}	SAL 10^{-6}	SAL 10^{-6}	SAL 10^{-6}	

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User Population	**Prescription**	Prescription Only	Prescription Only	Prescription Only	Prescription Only	Prescription Only	SAME AS PREDICATE The subject device and the predicate devices are prescription only devices that serve the same user populations.
	Intended User	Surgeons trained in endoscopic, and/or laparoscopic techniques and/or interventional radiologists.	Surgeons trained in endoscopic and/or laparoscopic techniques	Surgeons trained in endoscopic techniques	Various clinicians trained in the use of sutures	Surgeons, gastrointestinal doctors, and interventional radiologists	
Clinical Application	**Indications for Use**	Indicated to pass suture through soft tissues of the body during endoscopic/laparoscopic surgery and interventional radiology procedures in child, adolescent and adult populations.	Indicated to pass suture through soft tissues of the body during endoscopic/ laparoscopic surgery	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	Indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, orthopedic and neurological procedures	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	SIMILAR TO PREDICATE The subject device differs from the predicate in the addition of interventional radiology procedures to the indications for use, and in the inclusion of the patient population in the indications for use. Expansion of the indication to IR procedures is supported because the subject device allows contrast to be injected through the device.
	Intended Use	Passes a suture through soft tissues of the body	Passes a suture through soft tissues of the body	Passes a suture through soft tissues of the body for the purpose of securing a hollow viscus to the anterior abdominal wall	Approximation and/or ligation of soft tissues	Delivers a suture with a metal anchor through soft tissues of the body for the purpose of securing the stomach to anterior the abdominal wall	

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	Procedural Use	General surgery	General surgery	Pexy procedures (e.g., gastropexy, jejunopexy, cystopexy, etc.)	General surgery (including cardiovascular, ophthalmic, orthopedic and neurological procedures)	Gastropexy	The addition of the patient population to the indications is keeping in line with current best practices for device labeling.
MR Safety	**Device**	Not MR-safe	Not MR-safe	Not MR-safe	N/A – SUTURE ONLY	Not MR-safe	SAME AS PREDICATE Neither the subject device nor the predicate devices are MR-safe. Suture placed using any of the devices is MR-safe when placed in accordance with the labeling.
	Suture	For the configuration which features magnetically assisted end-effectors, suture is MR-safe after magnet head is removed	*Suture not included, but required in accordance with labeling. Suture is MR-safe after needle is removed.	Suture is MR-safe after magnet head is removed	Suture is MR-safe after needle is removed	Suture is MR-conditional due to metal T-bar anchor that remains inside the patient after placement	
Configurations	**Instrument Kit(s)**	For the configuration which features magnetically assisted end-effectors, YES – AMT Suture Passer Kit	For the configuration that features port closure elements, YES – Carter-Thomason II Port Closure System	NO	NO	YES – Gastropexy Kit	SIMILAR TO PREDICATE The subject device uses a small gauge needle that is shorter than the predicate and may be offered in curved configurations. The subject device utilizes an echogenic treatment on the needle.
	Needle Sizes	17-gauge: May be offered curved or straight, depending on configuration.	14-gauge	17-gauge	Multiple sizes: Needle size scales with suture size	18-gauge	

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	Needle Length	2.5 in. [6.35 cm]	8.3 in. [120.82 cm]	2.5 in. [6.35 cm]	Multiple sizes available (needle size scales relative to suture size)	7 cm	Suture is included with one configuration of the subject device, but must be furnished by the user with the other and the predicate.
	Needle Type	Hypodermic (hollow, round cross-section)	Hypodermic (hollow, round cross-section)	Hypodermic (hollow, round cross-section)	Solid, available in multiple cross-sectional shapes	Hypodermic (hollow, round cross-section)	
	Needle Finish	As-drawn; echogenic treatment	As-drawn	As-drawn	Machined/ground	As-drawn	
	Suture Size	For the configuration which features magnetically assisted end-effectors, USP 3-0	*Suture not included. Recommended size is USP 1	USP 3-0	USP 7-0 through 9	USP 2-0	
Technological Characteristics	**Design Archetype**	Grasper-type suture passer	Grasper-type suture passer	Magnetic suture passer	Surgical suture	T-bar suture anchor	SIMILAR TO PREDICATE Both the subject device and the Carter-Thomason predicate device follow the same design archetype and have the same operational style. Both devices utilize similar means of suture securement, and both work with standard surgical sutures.
	Operational Style	Hand-held; manually operated / no external power source	Hand-held; manually operated / no external power source	Hand-held; manually operated / no external power source	Hand-held; manually operated / no external power source	Hand-held; manually operated / no external power source	
	Suture Securement Method	Suture mechanically trapped between grasper and wall of needle	Suture mechanically trapped between grasper and wall of needle	Suture coupled to retriever by magnetic connection	Manual (needle driver, etc.)	N/A (suture is not retrieved using device)	

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Compatible Suture	Compatible with standard surgical sutures and magnetic sutures, depending upon configuration	Compatible with standard surgical sutures	Compatible with included magnetic suture	N/A	Compatible with included T-bar suture	The subject device differs from the Carter-Thomason predicate in the use of magnet technology and provision for fluid exchange through the device.
Suture Specification	For the configuration which features magnetically assisted end-effectors, USP 3-0, polyester, braided, nonabsorbable, magnetic head	*Suture not included (USP size 1 recommended)	USP 3-0, polyester, braided, nonabsorbable, magnetic head	USP 7-0 through 9, polyester, braided, nonabsorbable, needle head	USP 3-0, Byosyn, monofilament, absorbable, T-bar head	
Magnet Technology	ONLY for the configuration which features magnetically assisted end-effectors - small permanent gold-plated magnets (NdFeB) incorporated into grasper arm and suture head	NO	Small permanent gold-plated magnets (NdFeB) incorporated into retriever arm and suture head	NO	NO	
Fluid Exchange	Luer-lock compatible hub for syringe attachment; patent lumen through device	NO	NO	N/A	Luer-lock compatible hub for syringe attachment; patent lumen through device	

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Construction	**Main Components**	• Instrument body w/ hypodermic needle(s) • Grasper assembly • Lock assembly • Suture with magnet head, for the configuration which features magnetically assisted end-effectors	• Instrument body w/ hypodermic needle • Grasper assembly • Port-closure elements ONLY with the Carter-Thomason II Port Closure System	• Instrument body w/ hypodermic needles (2) • Magnetic suture delivery cannula assembly • Magnetic suture retrieval probe assembly • Suture with magnet head • Skin bumper	• Suture with needle head	• Instrument body w/ hypodermic needle • T-bar suture delivery cannula assembly • Suture with T-bar head • Skin bumper/ suture clip	SIMILAR TO PREDICATE The main components that comprise the subject device are similar to the predicate, differing in the inclusion of magnetic sutures for the relevant configuration and a locking mechanism.
	Materials of Construction	• 300-series Stainless steel • Nitinol • Thermoplastics • Adhesives • Gold-plated neodymium (magnets), ONLY for the configuration which features magnetically assisted end-effectors	• 300-series Stainless steel • Thermoplastics • Adhesives	• 300-series Stainless steel • Nitinol • Gold-plated neodymium (magnets) • Thermoplastics • Adhesives • Silicone	• 300- or 400-series Stainless steel or Maraging Steel • Thermoplastics	• 300-series Stainless steel • Thermoplastics • Bio-absorbable thermoplastics • Adhesives	

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Construction (Cont.)	**Manufacturing Processes**	• Thermoplastic Injection Molding • Thermoplastic Extrusion • Progressive Die Stamping • DOM Tube Forming • Bending/ Coiling • Filament Extrusion + Braiding • Cutting/ Grinding/ Machining • Shape Setting • Assembly with UV-Cured Adhesives • Assembly with Cyanoacrylates • Assembly without Adhesives • Swaging/ Crimping • Powdered Metallurgy + Gold Plating, ONLY for the configuration which features magnetically assisted end-effectors	• Thermoplastic Extrusion • Thermoplastic Injection Molding • Metal Stamping • DOM Tube Forming • Bending/ Coiling • Cutting/ Grinding/ Machining • Assembly with Adhesives • Assembly without Adhesives	• Thermoplastic Injection Molding • Thermoplastic Extrusion • Silicone Injection Molding • Silicone Extrusion • Progressive Die Stamping • DOM Tube Forming • Bending/ Coiling • Filament Extrusion + Braiding • Cutting/ Grinding/ Machining • Powdered Metallurgy + Gold Plating • Autogenous Welding + Shape Setting • Assembly with UV-Cured Adhesives • Assembly with Cyanoacrylates • Assembly without Adhesives • Swaging/ Crimping	• Filament Extrusion + Braiding • Cutting/ Grinding/ Machining • Assembly without Adhesives • Swaging/ Crimping	• Thermoplastic Injection Molding • Silicone Injection Molding • DOM Tube Forming • Filament Extrusion • Cutting/ Grinding/ Machining • Assembly with Adhesives • Assembly without Adhesives • Swaging/ Crimping	SIMILAR TO PREDICATE The subject device employs manufacturing processes that are similar to the predicate devices. The differences that exist between the subject device and predicate device are related to the differences in components described above (e.g., powdered metallurgy + gold plating relates to the construction of the permanent magnets, etc. ONLY for the configuration which features magnetically assisted end-effectors – components which are not found in the predicate device).

VII. PERFORMANCE DATA:

A. Biocompatibility Testing: Following a Biological Evaluation Plan, the AMT Suture Passer was tested for biocompatibility based on the applicable sections of the following standards:

- ISO 10993-1 Fifth edition 2018-08 - Biological evaluation of medical devices --Part 1: Evaluation and testing within a risk management process
- ISO 10993-5 Third edition 2009-06-01 - Biological evaluation of medical devices --Part 5: Tests for in vitro cytotoxicity
- ISO 10993-7 Second edition 2008-10-15 - Biological evaluation of medical devices --Part 7: Ethylene oxide sterilization residuals
- ISO 10993-10 Fourth edition 2021-11 - Biological evaluation of medical devices --Part 10: Tests for skin sensitization
- ISO 10993-11 Third edition 2017-09 - Biological evaluation of medical devices --Part 11: Tests for systemic toxicity
- ISO 10993-23 First edition 2021-01 - Biological evaluation of medical devices --Part 23: Tests for irritation
- USP-NF M98830_02_01 <85> Bacterial Endotoxins Test
- USP-NF M98910_01_01 <161> Medical Devices – Bacterial Endotoxin and Pyrogen Tests

It was determined that the AMT Suture Passer met the acceptance criteria for limited contact (24 hours or less) with tissue/bone/dentin. The suture component of the subject device met the acceptance criteria for prolonged contact (greater than 24 hours to 30 days) with tissue/bone/dentin.

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

C. Electromagnetic Compatibility & Electrical Safety: There are no electronic components related in any way to this device.

D. Performance Testing:

1. Sterilization

Testing has been completed to evaluate the sterilization process for the subject device, and is outlined below:

- Testing per ISO 10993-7, Second edition 2008-10-15
    - Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals

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

Applicable shelf life testing was conducted in accordance with the following:

- Testing per ISO 11607-1 & 2, Second edition 2019-02:
  - Packaging for terminally sterilized medical devices
- Testing per ISTA 3A 2018:
  - Packaged products for parcel delivery system shipment 70kg (150 lb) or less

Testing indicates that the subject device has a validated shelf life of three (3) years.

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 include:

- Testing per ISO 7864 Fourth edition 2016-08-01
  - Sterile hypodermic needles for single use – Requirements and test methods
- Testing per ISO 9626 Second edition 2016-08-01
  - Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods
- Testing per USP-NF M99670_02_01
  - <881> Tensile Strength
- Testing per USP-NF M99660_03_01
  - <871> Sutures – Needle Attachment
- Testing per ISO 80369-1 Second edition 2018-11
  - Small-bore connectors for liquids and gases in healthcare applications – Part 1: General requirements
- Testing per ISO 80369-7 Second edition 2021-05
  - Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications

The AMT Suture Passer met or exceeded all the acceptance criteria and does not raise new questions of safety or effectiveness when compared to the predicate.

E. Animal Study: Animal testing was NOT performed.

F. Clinical Study: Clinical testing was NOT performed.

VIII. CONCLUSION:

The subject device is comparable in intended use, operative principles, materials of construction, methods of manufacture, and technology to the predicate devices and therefore do not raise new concerns regarding the safety or effectiveness of the subject device. Minor differences between the subject device and the predicate devices do not result in new concerns regarding safety and effectiveness, either. Therefore, the subject device may be claimed to be substantially equivalent to the predicate devices.