December 18, 2023

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

Re: K222846
Trade/Device Name: AMT G-Tube Balloon Gastrostomy Feeding Device
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube And Accessories
Regulatory Class: Class II
Product Code: KNT
Dated: November 17, 2023
Received: November 17, 2023

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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222846

Device Name
AMT G-Tube Balloon Gastrostomy Feeding Device

Indications for Use *(Describe)*
The AMT G-Tube Balloon Gastrostomy Feeding Device is indicated to be used as a percutaneous gastrostomy tube. This device will assist in providing nutrition directly into the stomach through a secured (initial placement) or formed (replacement) stoma in a human patient, 10kg or above, who is unable to consume nutrition by conventional means. The AMT G-Tube Balloon Gastrostomy Feeding Device can also deliver medication and allow for decompression of the stomach.

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 G-Tube Balloon Gastrostomy Feeding Device

I. SUBMITTER:

Applied Medical Technology, Inc.
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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: November 17, 2023

II. DEVICE INFORMATION:

Trade/Device Name: AMT G-Tube Balloon Gastrostomy Feeding Device
Common Name: Gastrointestinal Tube and Accessories
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KNT

III. PREDICATE INFORMATION:

Predicate: K161413 (Low Profile Balloon Feeding Device; Applied Medical Technology, Inc.)

Secondary Predicate Device: K190923 (Salem Sump Dual Lumen Stomach Tube with ENFit Connection; Cardinal Health).

Tertiary Predicate Device: K971434 (AMT G-Tube Balloon Replacement Gastrostomy Feeding Device; Applied Medical Technology, Inc.)

**** None of the predicate devices have been subject to design-related recalls.**

IV. INDICATIONS FOR USE:

The AMT G-Tube Balloon Gastrostomy Feeding Device is indicated to be used as a percutaneous gastrostomy tube. This device will assist in providing nutrition directly into the stomach through a secured (initial placement) or formed (replacement) stoma in a human patient, 10kg or above, who is unable to consume nutrition by conventional means. The AMT G-Tube Balloon Gastrostomy Feeding Device can also deliver medication and allow for decompression of the stomach.

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V. DEVICE DESCRIPTION:

The Applied Medical Technology, Inc. G-Tube Balloon Gastrostomy Feeding Device (AMT G-Tube) is made of silicone elastomer and is designed for enteral feeding in a gastrostomy tract. The device can be used as a replacement device through a mature stoma tract or for initial placement in a supported stoma tract.

The device is offered in several French (FR) sizes ranging from 12 FR to 24 FR. On the shaft near the end is located a balloon which, when properly inflated acts as an internal stabilizer preventing outward displacement through the stoma in the abdominal wall. The balloon is inflated through a separate inflation valve located in the external portion of the device. The external bolster (pre-assembled on the AMT G-Tube) acts as a stabilizer to prevent inward migration.

The device is sold as sterile and can be placed in an outpatient or home setting by a health care professional or care giver.

For G-Tubes *without* Enhanced Decompression Capabilities:

The device has a "Y" port on one end. On this end there are three openings. One for the luer syringe to fill the balloon (contains a fill valve in this opening). One for attaching external tubing for feeding. One for administering medication if required (also known as a med port). The Y-Port has flexible caps for closing off the feeding and med ports when not in use. The silicone balloon is bonded on the other end of the G-Tube and a separate channel through the tubing connects the balloon to the balloon filling port and valve. The balloon filling port contains the valve required to fill and deflate the balloon using a luer syringe.

For G-Tubes *with* Enhanced Decompression Capabilities:

The device has a "Y" port on one end. On this end there are three openings. One for the luer syringe to fill the balloon (contains a fill valve in this opening). When not utilizing the decompression capability of the device, the large, main port will be used for attaching external tubing/syringe for feeding and medication. When decompressing the stomach is required, this same large, main port will be attached to external suction for decompression. During decompression, the smaller side port on the "Y" port will open to provide make-up air to the stomach. The Y-Port has flexible caps for closing off the main and side ports when not in use. The silicone balloon is bonded along the tubing of the G-Tube, and a separate channel through the tubing connects the balloon to the balloon fill port and valve. The balloon fill port contains the valve required to fill and deflate the balloon using a luer syringe.

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VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATES:

TABLE 5.1- TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT DEVICE AND THE PREDICATE DEVICES

	Subject Device:	Predicate (K161413):	Secondary Predicate (K190923):	Tertiary Predicate (K971434):
Device Class and Product Code:	Class II; KNT	Class II; KNT	Class II; PIF, FEG	Class II; KNT
	Substantial Equivalence:	Same	Different	Same
Sterilization:	Sterile (Ethylene Oxide), single use only	Sterile (Ethylene Oxide), single use only	Sterile (Ethylene Oxide), single use only	Sterile (Ethylene Oxide), single use only
	Substantial Equivalence:	Same	Same	Same
Prescription	Single use: Prescription Only.	Single use: Prescription Only.	Single use: Prescription Only.	Single use: Prescription Only.
	Substantial Equivalence:	Same	Same	Same
Indications for Use:	The AMT G-Tube Balloon Gastrostomy Feeding Device is indicated to be used as a percutaneous gastrostomy tube. This device will assist in providing nutrition directly into the stomach through a secured (initial placement) or formed (replacement) stoma in a human patient, 10kg or above, who is unable to consume nutrition by conventional means. The AMT G-Tube Balloon Gastrostomy Feeding Device can also deliver medication and allow for decompression of the stomach.	The Low Profile Balloon Feeding Device is indicated for use in patients who require long term feeding, are unable to tolerate oral feeding, who are at low risk for aspiration, require gastric decompression and/or medication delivered directly into the stomach through a secured (initial placement) or formed (replacement) stoma. The Low Profile Balloon Feeding Device is intended for all age groups.	The Salem Sump™ Dual Lumen Stomach Tube with ENFit™ Connection is intended for gastric decompression and administration of nutrition, fluids and medication. The device is intended for patients with age of two and older.	The AMT Balloon G-Tube is to be used as a percutaneous replacement gastrostomy tube for a patient with a well-established gastrostomy tract. This device will assist in providing nutrition directly into the stomach through an established stoma in a human patient who is unable to consume nutrition by conventional means. The AMT Balloon G-Tube can also deliver medication and allow for decompression of the stomach.

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TABLE 5.1- TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT DEVICE AND THE PREDICATE DEVICES

	Subject Device:	Predicate (K161413):	Secondary Predicate (K190923):	Tertiary Predicate (K971434):
	Substantial Equivalence:	Similar	Similar	Similar
Intended Use:	To provide nutrition directly into the stomach through a secured (initial placement) or formed (replacement) stoma in a human patient who is unable to consume nutrition by conventional means. The device does not require endoscopy for removal or replacement.	The Low Profile Balloon Feeding Device is indicated for use in patients who require long term feeding, are unable to tolerate oral feeding, who are at low risk for aspiration, require gastric decompression and/or medication delivered directly into the stomach through a secured (initial placement) or formed (replacement) stoma. The Low Profile Balloon Feeding Device is intended for all age groups.	The Salem Sump™ Dual Lumen Stomach Tube with ENFit™ Connection is intended for gastric decompression and administration of nutrition, fluids and medication. The device is intended for patients with age of two and older.	To provide nutrition directly into the stomach through an established stoma in a human patient who is unable to consume nutrition by conventional means. The G-Tube Balloon Replacement Gastrostomy Feeding Device is meant to be a replacement device, not an initially placed feeding tube. The device does not require endoscopy for removal or replacement. The device is designed in several sizes to accommodate the pediatric as well as the adult patient.
	Substantial Equivalence:	Similar	Similar	Similar
Principles of Operation	The device features a bi-lumen silicone tube overmolded on one end with a silicone Y-port through which nutrition and medication may be delivered. Opposite the Y-port, the tubing is defined on one end with an inflatable silicone balloon that acts as an internal bolster to prevent outward migration of the device. Along the tubing, between the Y-port and Balloon, is a sliding	The device features a bi-lumen silicone tube overmolded on one end with a low-profile silicone bolster through which nutrition and medication may be delivered, by way of polycarbonate interlock. Opposite the bolster, the tubing is tipped on one end with a special silicone tip, bonded directly to an inflatable silicone	One lumen is used as the primary channel for nutrition and medication delivery, while the second lumen serves as a vent channel and allows make-up air to be drawn into the stomach when Gastric Decompression is performed through the primary lumen – reducing the chance that the suction causes ulceration of the mucosa of the stomach wall	The device features a bi-lumen silicone tube overmolded on one end with a silicone Y-port through which nutrition and medication may be delivered. Opposite the Y-port, the tubing is tipped on one end with an inflatable silicone balloon that acts as an internal bolster to prevent outward migration of the device. Along the tubing, between the Y-port and Balloon, is a sliding

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TABLE 5.1- TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT DEVICE AND THE PREDICATE DEVICES				
	Subject Device:	**Predicate (K161413):**	**Secondary Predicate (K190923):**	**Tertiary Predicate (K971434):**
	external bolster that is positioned snug to the abdomen to prevent inward migration. Those configurations that feature Enhanced Decompression are made with tri-lumen tubing and additional tubing length distal to the balloon, creating a "sump" to reach the dependent portion of the stomach and providing a lumen the full length of the device to allow make-up air to be drawn into the stomach when Gastric Decompression is performed through the primary lumen – reducing the chance that the suction causes ulceration of the mucosa of the stomach wall during Low Intermittent Wall Suction.	balloon that acts as an internal bolster to prevent outward migration of the device.	during Low Intermittent Wall Suction.	external bolster that is positioned snug to the abdomen to prevent inward migration.
	Substantial Equivalence:	Similar	Similar	Similar
Design Similarities	1. Devices have direct access to stomach. 2. All devices have the ability to decompress the stomach. 3. All devices have the ability to administer feeding solutions and medications directly into the stomach. 4. All devices are offered in various French sizes for adult and pediatric use.			

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TABLE 5.1- TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT DEVICE AND THE PREDICATE DEVICES

	Subject Device:	Predicate (K161413):	Secondary Predicate (K190923):	Tertiary Predicate (K971434):
Design Differences	1. The G-Tube and low-profile devices are anchored in the stomach with a silicone retention balloon, while the Salem Sump device is not anchored. 2. The G-Tube and low-profile devices directly access the stomach via a stoma tract, while the Salem Sump device is a naso/orogastric device. 3. The G-Tube and low-profile devices are predominately made of silicone, while the Salem Sump device is predominately made of polyvinyl chloride (PVC). 4. The G-Tube with Enhanced Decompression Capabilities and the Salem Sump utilize a dedicated "vent" lumen to allow make-up air to enter the stomach during decompression to allow for more effective gastric decompression while those G-Tube configurations without Enhanced Decompression features as well as the low-profile device do not feature a dedicated vent lumen. 5. The G-Tube devices have a sliding external bolster to help secure the device within the patient, while the Salem Sump and low-profile devices do not have a sliding component. 6. The low-profile device is configured in fixed lengths to be selected for certain abdominal wall thicknesses while the other devices are adjustable across a range of patient anatomy.			

VII. PERFORMANCE DATA:

A. Biocompatibility Testing: Following a Biological Evaluation Report, the AMT G-Tube Balloon Gastrostomy Feeding Device was tested for biocompatibility based on the applicable sections of the following standards:

- ISO 10993-1:2018 Biological Evaluation of Medical Devices
  --Part 1: Evaluation and Testing Within a Risk Management Process
- ISO 10993-3 Biological Evaluation of Medical Devices
  --Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity
- ISO 10993-5:2009 Biological Evaluation of Medical Devices
  --Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-6:2016 Biological Evaluation of Medical Devices
  --Part 6: Tests for Local Effects After Implantation
- ISO 10993-7:2008 Biological Evaluation of Medical Devices
  --Part 7: Ethylene Oxide Sterilization Residuals
- ISO 10993-10:2010 Biological Evaluation of Medical Devices
  --Part 10: Tests for Irritation and Skin Sensitization
- ISO 10993-11:2017 Biological Evaluation of Medical Devices
  --Part 11: Tests for Systemic Toxicity

In accordance with a Biological Evaluation Report, a Biological Risk Assessment was completed on the patient contacting materials and it was determined that the AMT G-Tube Balloon Gastrostomy Feeding Device met the acceptance criteria for permanent contact (greater than 30 days) with mucosal membrane and breached/compromised surfaces.

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B. Performance Testing:

1. Sterilization

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

- Testing per ANSI/AAMI/ISO 11135-1:2014
  - Sterilization process validation

- Testing per ISO 10993-7:
  - 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 in accordance with ASTM F1980:

  - Evaluation of the performance of the Traditional GJ device after a simulated 3-year accelerated aging of packaging

- Testing in accordance with ASTM F1980-16:

  - Evaluation of the performance of 50A durometer 18Fr TGJ assemblies after four years of accelerated aging

  - Evaluation of the performance of 50A durometer 18Fr TGJ sprung tubing after a four-year accelerated aging simulation

Testing indicates that the subject device has a validated shelf life of three 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. All testing was performed to ensure conformity to ISO 14971 (application of risk management to medical devices). The tests carried out included:

- Testing per AMT Design Specifications:
  - Balloon Assembly Bond Peel/Tear Strength
  - Balloon Burst
  - Fill Valve Blow Out

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- Fill Valve Pullout
- Flow Rate
- Leak Test
- Tubing Tensile Test to determine strength (tested at gastric holes (for configurations with Enhanced Decompression Capabilities))
- Minimum Overmold Bond Strength
- Stoma Pullout
- Tubing Cyclic and Tensile Test
- Main Strap Tensile Test
- Side Strap Tensile Test

- Testing per ASTM F2528-06
  - Balloon Integrity in Simulated Gastric Fluid
  - Balloon volume maintenance
  - Balloon size and shaft size
  - Balloon concentricity
  - Balloon integrity

- Testing per ISO 80369-3
  - Dimensional Verification
  - Missed Connection Testing

- Testing per ISO 80369-20:
  - Fluid leakage
  - Stress cracking
  - Resistance to separation from axial load
  - Resistance to separation from unscrewing
  - Resistance to overriding
  - Disconnection by unscrewing

- Testing per ISO 11607-1:2019 and ISO 11607-2:2019
  - Packaging for terminally sterilized medical devices

- Testing per EN 1615:2000, EN 1618:1997
  - Leak Testing

- Testing per (USP) 41-National Formulary (NF) 36: 2018 <151>
  - Pyrogenicity testing

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

C. Animal Study: Animal testing was NOT performed.

D. Clinical Study: Clinical testing was NOT performed.

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E. CONCLUSION:

The AMT G-Tube Balloon Gastrostomy Feeding Device can be found substantially equivalent to the predicate device cleared under K161413 in intended use, performance, and principles of operation. The design differences between the subject device and the predicate device 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 predicate device.