March 1, 2019

Applied Medical Technology, Inc.
Joy Tubero
Regulatory Affairs Specialist
8006 Katherine Boulevard
Brecksville, OH 44141

Re: K182804
Trade/Device Name: Traditional Length GJ Feeding Device
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KNT, PIF
Dated: January 23, 2019
Received: January 28, 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark J. Antonino -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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)*
K182804

Device Name
Traditional Length GJ Feeding Device

Indications for Use *(Describe)*
The Traditional Length GJ Feeding Device is indicated for use in adult, adolescent, children, and infant patients over 10kg who cannot absorb adequate nutrition through the stomach, who have intestinal motility problems, gastric outlet obstruction, severe gastroesophageal reflux, are at risk of aspiration, or in those who have had previous esophagectomy or gastrectomy.

The use of this tube is also clinically indicated when simultaneous gastric decompression and jejunal feeding are needed. This includes patients in whom malnutrition already exists, or may result, secondary to concurrent conditions.

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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*"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."*

# SECTION – 5

## 510(k) Summary

Traditional Length GJ Feeding Device

### 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 Affairs Specialist
**Email:** joy.tubero@appliedmedical.net
**Date Prepared:** January 23, 2019

### II. DEVICE INFORMATION:

**Trade/Device Name:** Traditional Length GJ Feeding Device
**Common Name:** Gastrointestinal Tube
**Classification Name:** Gastrointestinal tubes and accessories. (21 CFR 876.5980)
**Product Code:** KNT, PIF
**Regulatory Class:** II
**Review Panel:** Gastroenterology and Urology

### III. PREDICATE INFORMATION:

**Primary Predicate:** AMT Low-Profile Transgastric-Jejunal Feeding Tube Kit (K123716)

- The predicate device has **not** been subject to design-related recalls.

### IV. INDICATIONS FOR USE:

The Traditional Length GJ Feeding Device is indicated for use in adult, adolescent, child, and infant patients over 10kg who cannot absorb adequate nutrition through the stomach, who have intestinal motility problems, gastric outlet obstruction, severe gastroesophageal reflux, are at risk of aspiration, or in those who have had previous esophagectomy or gastrectomy.

The use of this tube is also clinically indicated when simultaneous gastric decompression and jejunal feeding are needed. This includes patients in whom malnutrition already exists, or may result, secondary to concurrent conditions.

# SECTION – 5

## V. DEVICE DESCRIPTION:

The Traditional Length GJ Feeding Device is a single-use feeding tube that provides for simultaneous gastric decompression / drainage and delivery of enteral nutrition into the distal duodenum or proximal jejunum. It enters the stomach through a surgically-created gastric stoma. The multi-lumen tubing is marked with a graduated scale and held in place by means of an inflatable internal retention balloon and a sliding external bolster. The external tri-port is overmolded onto the tubing and contains three ports: one large port for administering nutrition/medication in the jejunum labeled "**JEJUNAL**," one large port for gastric decompression/drainage labeled "**GASTRIC**," and one smaller port housing the balloon fill valve labeled "**BAL**."

The tri-port component of the Traditional Length GJ Feeding Device is offered in two variations: a legacy model and an ENFit® model designed to ISO 80369-3. Both variations of the device are identical except for the design of the tri-port component configurations.

1. The tri-port of the legacy model has two large silicone funnel ports, and a small port to fill the retention balloon. The JEJUNAL and the GASTRIC ports have individual attached silicone straps and plugs intended to independently close each funnel when not in use. The BAL port houses a small, MR conditional balloon fill valve.

2. The tri-port of the ENFit® model has 2 large ports and one small port akin to the legacy model, but with a twist-lock thermoplastic male ENFit® connector housed in each the JEJUNAL and the GASTRIC funnel ports. The ENFit® connectors are compliant to ISO 80369-3. The JEJUNAL and the GASTRIC ENFit® ports have individual attached tethers and plugs intended to independently close each ENFit® port when not in use. The BAL port houses an MR safe balloon fill valve.

Both the legacy and the ENFit® variations of the Traditional Length GJ Feeding Device are offered in different French sizes. The gastric length of both variations of the Traditional Length GJ Feeding Device is adjustable, depending on where the sliding external bolster is placed along the multi-lumen tubing. Various jejunal lengths are available. The distal portion of only the 16Fr and 18Fr jejunal tubing contains an anti-kink design using a metal spring. At the distal end of every tube, a silicone tip is attached to the device through which a non-absorbable suture is attached. The Traditional Length GJ Feeding Device is provided sterile (Ethylene Oxide) for prescription use only.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE:

| **TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT DEVICE AND THE PREDICATE DEVICE** | | |
|---|---|---|
| | **Subject Device: Traditional Length GJ Feeding Device** | **Predicate: AMT Low-Profile Transgastric-Jejunal Feeding Tube Kit (K123716)** |
| **Device Class and Product Code:** | II, KNT, PIF | II, KNT |
| | **Substantial Equivalence:** | Similar |

# SECTION – 5

| TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT DEVICE AND THE PREDICATE DEVICE | | |
|---|---|---|
| **Sterilization:** | Sterile (Ethylene Oxide), single use only. | Sterile (Ethylene Oxide), single use only. |
| | **Substantial Equivalence:** | Same |
| **Prescription** | Single use: Prescription Only | Single use: Prescription Only |
| | **Substantial Equivalence:** | Same |
| **MRI Safety Information** | Labeled MR Conditional | Labeled MR Conditional |
| | **Substantial Equivalence:** | Same |
| **Indications for Use:** | The Traditional Length GJ Feeding Device is indicated for use in adult, adolescent, child, and infant patients over 10kg who cannot absorb adequate nutrition through the stomach, who have intestinal motility problems, gastric outlet obstruction, severe gastroesophageal reflux, are at risk of aspiration, or in those who have had previous esophagectomy or gastrectomy.<br><br>The use of this tube is also clinically indicated when simultaneous gastric decompression and jejunal feeding are needed. This includes patients in whom malnutrition already exists, or may result, secondary to concurrent conditions. | The AMT Transgastric-Jejunal feeding tube is indicated for use in patients who cannot absorb adequate nutrition through the stomach, who have intestinal motility problems, gastric outlet obstruction, severe gastroesophageal reflux, are at risk of aspiration, or in those who have had previous esophagectomy or gastrectomy.<br><br>The use of this tube is also clinically indicated when simultaneous gastric decompression and jejunal feeding are needed. This includes patients in whom malnutrition already exists, or may result, secondary to concurrent conditions. |
| | **Substantial Equivalence:** | Similar |
| **Intended Use:** | Provide simultaneous gastric decompression/drainage and delivery of enteral nutrition into the distal duodenum or proximal jejunum. | Provide simultaneous gastric decompression/drainage and delivery of enteral nutrition into the distal duodenum or proximal jejunum. |
| | **Substantial Equivalence:** | Same |
| **Principles of Operation** | • Deliver enteral nutrition directly into the small intestine by enteral feeding pump.<br>• Allow gastric decompression by gravity (leaving the G plug open), or connect to low intermittent suction. | • Deliver enteral nutrition directly into the small intestine by enteral feeding pump.<br>• Allow gastric decompression by gravity (connect extension set to gastric port, leaving the plug open), or connect to low intermittent suction. |
| | **Substantial Equivalence:** | Similar |

## SECTION – 5

| TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT DEVICE AND THE PREDICATE DEVICE | | |
|---|---|---|
| **Major Design Characteristics** | • Medical grade silicone construction<br>• Medical grade silicone tubing with graduated centimeter markings<br>• Sliding external bolster<br>• External tri-port adapter:<br>o Jejunal feeding port with strap/plug<br>o Gastric decompression port with strap/plug<br>o Balloon fill valve<br>• Inflatable silicone internal retention balloon<br>• Multiple Gastric and Jejunal exit ports<br>• Anti-kink enforced Jejunal portion (16Fr & 18Fr only)<br>• Tapered distal tip with suture<br>• MR Conditional | • Medical grade silicone construction<br>• Medical grade silicone tubing<br>• External low-profile bolster:<br>o Jejunal feeding port with interlock and strap/plug<br>o Gastric decompression port with interlock and strap/plug<br>o Balloon fill valve<br>• Inflatable silicone internal retention balloon<br>• Multiple Gastric and Jejunal exit ports<br>• Anti-kink enforced Jejunal portion (16Fr & 18Fr only)<br>• Tapered distal tip with suture<br>• MR Conditional |
| | **Substantial Equivalence:** | Similar |

As indicated above, minor differences exist between the Traditional Length GJ Feeding Device and the predicate device. These differences include:

- External device profile/size: The subject device has a tri-port (overmold) attached to a standard length of adjustable gastric tubing available in various jejunal lengths while the primary predicate is not adjustable, but rather has a low-profile (overmold) bolster attached to various gastric and jejunal length configurations.

These minor design differences between the Traditional Length GJ Feeding Device (subject device) and the primary predicate (K123716) device do not raise different questions of safety and/or effectiveness from the predicate device. The intended use and indications for use remain the same between the Traditional Length GJ Feeding Device and the predicate device.

### VII. PERFORMANCE DATA:

**A. Biocompatibility Testing:** Following a Biological Evaluation Plan, the Traditional Length GJ Feeding Device has been tested for biocompatibility based on the applicable sections of the following standards:

- ISO 10993-1: 2009 Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process
- ISO 10993-3: 2014 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: Test for local effects after implantation.
- ISO 10993-7: 2008 Biological Evaluation of Medical Devices

**SECTION – 5**

– Part 7: Ethylene Oxide Sterilization Residuals.
- ISO 10993-10: 2010 Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization.
- ISO 10993-11:2006 Biological Evaluation of Medical Devices – Part 11: Tests for systemic toxicity
- ISO 10993-12:2012 Biological Evaluation of Medical Devices – Part 12: Sample preparation and reference materials
- ISO 10993-17:2002 Biological Evaluation of Medical Device – Part 17: Sample preparation and reference materials

In accordance with a Biological Evaluation Plan, a Biological Risk Assessment was completed on the patient contacting materials and it was determined that the Traditional Length GJ Feeding Device met the acceptance criteria for permanent contact (greater than 30 days) with mucosal membrane and breached/compromised surfaces.

**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:**

AMT conducted various performance tests on the components contained within the Traditional Length GJ Feeding Device. Testing found that all components and materials met or exceeded design specifications established by AMT.

Bench tests have been carried out to demonstrate conformance to applicable recognized standards, as well as to compare performance to the predicate. The tests carried out are outlined below.

- Testing per AMT Design Specifications:
  - Balloon Assembly Bond Peel/Tear Strength
  - Balloon Burst
  - Fill Valve Blow Out
  - Fill Valve Pullout
  - Flow Rate
  - Leak Test
  - Tensile Test to tear tubing at jejunal holes
  - Tensile Test to tear tubing at gastric holes
  - Minimum Overmold Tri-Port Bond Strength
  - Stoma Pullout
  - Tubing Tensile Test
  - Suture Pullout Tensile Test
  - Gastric Strap Tensile Test
  - Jejunal Strap Tensile Test

- Testing per ASTM F2528-06:
  - Balloon Integrity in Simulated Gastric Fluid

**SECTION – 5**

- Balloon volume maintenance
- Balloon size and shaft size
- Balloon concentricity
- Balloon integrity

- 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 ASTM F2052:
  - Magnetically induced displacement force

- Testing per ASTM F2213:
  - Magnetically induced torque

- Testing per ASTM F2119:
  - MR image artifact

- Testing per ASTM F2182:
  - Radio frequency induced heating

The Traditional Length GJ Feeding Device meets all the acceptance criteria and performed comparable to or better than the primary predicate.

**E. Animal Study:** Animal testing was NOT performed.

**F. Clinical Study:** Clinical testing was NOT performed. Clinical evidence gathered from independent organizations has been included in the submission.

**VIII. Conclusion:**

The Traditional Length GJ Feeding Device can be found substantially equivalent to the primary predicate device cleared under K123716 in intended use, performance, and principles of operation. The minor design differences between the subject device and the legally marketed predicate do not raise different questions of safety and/or efficacy, and the information submitted in this application demonstrates that the subject device is at least as safe and effective as the current legally marketed device.