March 29, 2019

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

Re: K183508
Trade/Device Name: Micro Transgastric-Jejunal Feeding Device
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KNT, PIF
Dated: February 25, 2019
Received: February 27, 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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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
Indications for Use

Micro Transgastric-Jejunal Feeding Device

Indications for Use (Describe)
The Micro Transgastric-Jejunal Feeding Device is indicated for use in children and adults 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)

- [x] 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.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASTaff@fda.hhs.gov

"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
Micro Transgastric-Jejunal 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: December 14, 2018

II. DEVICE INFORMATION:

Trade/Device Name: Micro Transgastric-Jejunal Feeding Device
Common Name: Gastrointestinal Tube
Classification Name: Gastrointestinal Tube And Accessories
Regulation Number: 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 Micro Transgastric-Jejunal Feeding Device is indicated for use in adult, adolescent, child, and infant patients over 6kg 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.
V. DEVICE DESCRIPTION:

The AMT Micro Transgastric-Jejunal 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 gastric stoma. The tube is held in place (within the stoma tract) by means of an inflatable balloon and a low-profile external bolster. The external bolster contains two ports; one labeled “JEJUNAL” (glow green) and one labeled “GASTRIC” (white). Incorporated within each port is a one-way valve which is opened by attaching the appropriate AMT Extension Set. AMT Extension Sets are color coded and connect to the feeding and drainage ports. The JEJUNAL (glow green) port is used for feeding into the small intestine. The GASTRIC (white) port is used to drain the stomach with the use of low intermittent suction or gravity drainage. A third port labeled “BAL” is used to inflate and deflate the balloon.

The Micro Transgastric-Jejunal Feeding Device is provided sterile (Ethylene Oxide) for prescription use only.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATES:

<table>
<thead>
<tr>
<th>TABLE 5.1- TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT DEVICE AND THE PREDICATE DEVICES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Device Class and Product Code:</strong></td>
</tr>
<tr>
<td>II, KNT, PIF</td>
</tr>
<tr>
<td><strong>Substantial Equivalence:</strong></td>
</tr>
<tr>
<td><strong>Sterilization:</strong></td>
</tr>
<tr>
<td><strong>Substantial Equivalence:</strong></td>
</tr>
<tr>
<td><strong>Prescription</strong></td>
</tr>
<tr>
<td><strong>Substantial Equivalence:</strong></td>
</tr>
<tr>
<td><strong>MRI Safety Information</strong></td>
</tr>
<tr>
<td><strong>Substantial Equivalence:</strong></td>
</tr>
</tbody>
</table>
### TABLE 5.1- TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT DEVICE AND THE PREDICATE DEVICES

<table>
<thead>
<tr>
<th>Subject Device: Micro Transgastric-Jejunal Feeding Device</th>
<th>Predicate: AMT Low-Profile Transgastric- Jejunal Feeding Tube Kit (K123716)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications for Use:</strong></td>
<td></td>
</tr>
<tr>
<td>The Micro Transgastric- Jejunal Feeding Device is</td>
<td>The AMT Transgastric-Jejunal feeding tube is</td>
</tr>
<tr>
<td>indicated for use in adult, adolescent, child, and infant</td>
<td>indicated for use in patients who cannot absorb adequate nutrition</td>
</tr>
<tr>
<td>patients over 6kg who cannot absorb adequate nutrition</td>
<td>through the stomach, who have intestinal motility problems, gastric</td>
</tr>
<tr>
<td>through the stomach, who have intestinal motility</td>
<td>outlet obstruction, severe gastroesophageal reflux, are at risk of</td>
</tr>
<tr>
<td>problems, gastric outlet obstruction, severe</td>
<td>aspiration, or in those who have had previous esophagectomy or</td>
</tr>
<tr>
<td>gastroesophageal reflux, are at risk of aspiration, or</td>
<td>gastrectomy. The use of this tube is also clinically indicated when</td>
</tr>
<tr>
<td>in those who have had previous esophagectomy or</td>
<td>simultaneous gastric decompression and jejunal feeding are needed.</td>
</tr>
<tr>
<td>gastrectomy. The use of this tube is also clinically</td>
<td>This includes patients in whom malnutrition already exists, or may</td>
</tr>
<tr>
<td>indicated when simultaneous gastric decompression and</td>
<td>result, secondary to concurrent conditions.</td>
</tr>
<tr>
<td>jejunal feeding are needed. This includes patients in</td>
<td></td>
</tr>
<tr>
<td>whom malnutrition already exists, or may result,</td>
<td></td>
</tr>
<tr>
<td>secondary to concurrent conditions.</td>
<td></td>
</tr>
<tr>
<td><strong>Substantial Equivalence:</strong></td>
<td>Similar</td>
</tr>
<tr>
<td><strong>Intended Use:</strong></td>
<td></td>
</tr>
<tr>
<td>Provide simultaneous gastric decompression/drainage and</td>
<td>Provide simultaneous gastric decompression/drainage and delivery of</td>
</tr>
<tr>
<td>delivery of enteral nutrition into the distal duodenum</td>
<td>enteral nutrition into the distal duodenum or proximal jejunum.</td>
</tr>
<tr>
<td>or proximal jejunum.</td>
<td></td>
</tr>
<tr>
<td><strong>Substantial Equivalence:</strong></td>
<td>Same</td>
</tr>
<tr>
<td><strong>Sizes:</strong></td>
<td></td>
</tr>
<tr>
<td>• Tube Diameter: larger proximal-gastric Fr size,</td>
<td>• Tube Diameter: entire length of device is one Fr size</td>
</tr>
<tr>
<td>smaller distal-jejunal Fr size</td>
<td></td>
</tr>
<tr>
<td><strong>Substantial Equivalence:</strong></td>
<td>Similar</td>
</tr>
<tr>
<td><strong>Principles of Operation</strong></td>
<td></td>
</tr>
<tr>
<td>• Deliver enteral nutrition directly into the small</td>
<td>• Deliver enteral nutrition directly into the small intestine by enteral</td>
</tr>
<tr>
<td>intestine by enteral feeding pump.</td>
<td>feeding pump.</td>
</tr>
<tr>
<td>• Allow gastric decompression by gravity (connect</td>
<td>• Allow gastric decompression by gravity (connect extension set to</td>
</tr>
<tr>
<td>extension set to gastric port, leaving the plug open),</td>
<td>gastric port, leaving the plug open), or connect to low intermittent</td>
</tr>
<tr>
<td>or connect to low intermittent suction.</td>
<td>suction.</td>
</tr>
<tr>
<td><strong>Substantial Equivalence:</strong></td>
<td>Same</td>
</tr>
</tbody>
</table>
TABLE 5.1- TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT DEVICE AND THE PREDICATE DEVICES

<table>
<thead>
<tr>
<th>Subject Device: Micro Transgastric-Jejunal Feeding Device</th>
<th>Predicate: AMT Low-Profile Transgastric-Jejunal Feeding Tube Kit (K123716)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Medical grade silicone and polyurethane construction</td>
<td>• Medical grade silicone construction</td>
</tr>
<tr>
<td>• External low-profile bolster:</td>
<td>• External low-profile bolster:</td>
</tr>
<tr>
<td>o Jejunal feeding port with interlock and strap/plug</td>
<td>o Jejunal feeding port with interlock and strap/plug</td>
</tr>
<tr>
<td>o Gastric decompression port with interlock and strap/plug</td>
<td>o Gastric decompression port with interlock and strap/plug</td>
</tr>
<tr>
<td>o Balloon fill valve</td>
<td>o Balloon fill valve</td>
</tr>
<tr>
<td>• Anti-reflux duckbill valves to help prevent leakage</td>
<td>• Anti-reflux duckbill valves to help prevent leakage</td>
</tr>
<tr>
<td>• Inflatable silicone internal retention balloon</td>
<td>• Inflatable silicone internal retention balloon</td>
</tr>
<tr>
<td>• Gastric and jejunal exit ports</td>
<td>• Gastric and Jejunal exit ports</td>
</tr>
<tr>
<td>• Anti-kink enforced Jejunal tubing</td>
<td>• Anti-kink enforced Jejunal portion of tubing (16Fr &amp; 18Fr only)</td>
</tr>
<tr>
<td>• Tapered distal tip</td>
<td>• Tapered distal tip with suture</td>
</tr>
<tr>
<td>• Radiopaque barium sulfate to aid in visualization</td>
<td>• Radiopaque barium sulfate to aid in visualization</td>
</tr>
<tr>
<td>• MR Conditional</td>
<td>• MR Conditional</td>
</tr>
<tr>
<td>• Sold as part of a kit with accessories</td>
<td>• Sold as part of a kit with accessories</td>
</tr>
</tbody>
</table>

Substantial Equivalence: Similar

As indicated above, minor differences exist among the Micro Transgastric-Jejunal Feeding Device and the predicate devices. These differences include:

- **Tubing Material**: The subject device tubing is composed of silicone and polyurethane while the predicate tubing is constructed of silicone tubing.
- **Size**: The subject device is offered with a distal/jejunal Fr size of tubing that is smaller than that of the proximal/gastric Fr size whereas the Fr size is consistent throughout the entire length of the predicate device.

These minor design differences between the Micro Transgastric-Jejunal Feeding Device (subject device), and the predicate (K123716) do not raise different questions of safety and/or effectiveness from the predicate or the reference device. The intended use and indications for use remain the same between the Micro Transgastric-Jejunal Feeding Device and the predicate device.

VII. PERFORMANCE DATA:

A. **Biocompatibility Testing**: Following a Biological Evaluation Plan, the Micro Transgastric-Jejunal 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
SECTION – 5

– 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
  – 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 Micro Transgastric-Jejunal 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 Micro Transgastric-Jejunal 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:
  o Balloon Assembly Bond Peel/Tear Strength
  o Balloon Burst
  o Fill Valve Blow Out
  o Fill Valve Pullout
SECTION – 5

- Flow Rate
- Leak Test
- Tensile Test to remove jejunal interlock
- Tensile Test to remove gastric interlock
- Tensile Test to tear tubing at jejunal hole
- Tensile Test to tear tubing at gastric hole
- Minimum Overmold External Bolster Bond Strength
- Stoma Pullout
- Tubing Tensile Test
- Gastric Strap Tensile Test
- Jejunal 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 80369-20:
  - 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 F2119:
  - MR image artifact

- Testing per ASTM F2182:
  - Radio frequency induced heating

The Micro Transgastric-Jejunal 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:
SECTION – 5

The Micro Transgastric-Jejunal Feeding Device can be found substantially equivalent to the 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.