DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 9, 2017

Applied Medical Technology, Inc.
Michelle Scott
Regulatory/QA Specialist
8006 Katherine Boulevard
Brecksville, OH 44141

Re: K161413
Trade/Device Name: Low Profile Balloon Feeding Device
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KNT
Dated: January 9, 2017
Received: January 10, 2017

Dear Michelle Scott:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161413

Device Name
Low Profile Balloon Feeding Device

Indications for Use *(Describe)*
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.

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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510(k) Summary

Low Profile Balloon Feeding Device

Date Prepared:	February 8, 2017
Submitter:	Applied Medical Technology, Inc. 8006 Katherine Boulevard Brecksville, OH 44141 Phone: 440-717-4000 Fax: 440-717-4200 Contact Person: Michelle Scott – Regulatory/QA Specialist Email: michelle.scott@appliedmedical.net
Device Information:	Trade/Device Name: Low Profile Balloon Feeding Device Common Name: Gastrointestinal Feeding Tubes Classification Name: Tubes, Gastrointestinal (And Accessories) (21 CFR 876.5980) Product Code: KNT Regulatory Class: II Review Panel: Gastroenterology and Urology
Predicate Device:	Primary Predicate: Kimberly-Clark MIC-KEY SF Low Profile Gastrostomy (K122653) Reference Device: Kimberly-Clark MIC-KEY Low Profile Gastrostomy Tube (K043114) Reference Device: Low Profile Balloon Feeding Device (K945618)
Intended Use:	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.
Device Description:	The Low Profile Balloon Feeding Device is used to provide nutrition, medication, and decompression access into the stomach through a secured (initial placement) or formed (replacement) stoma.
Technological Characteristics:	The Low Profile Balloon Feeding Device consists of an external bolster, feeding catheter, and internal retention balloon, similar to the predicate devices. The feeding catheter is inserted into the stomach through a stoma and is held in place with an internal retention balloon. The device can have an MR Conditional balloon fill-valve or will be MR Safe when assembled with the Invisi-Valve. The devices are provided in a number of sizes to accommodate different stoma

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	diameters and lengths and can have either a blunt or tapered tip balloon. The catheter tubes range in diameter from 10Fr to 24Fr, which is the same as the primary predicate. The stoma lengths are available in a wider range of options, from 0.5cm to 10.0 cm.
Biocompatibility Testing:	The Low Profile Balloon 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: 2003 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: 2007 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 10993-12:2007 Biological Evaluation of Medical Devices – Part 12: Sample preparation and reference materials An independent risk assessment was completed on the patient contacting materials and it was determined that the Low Profile Balloon Feeding Device met the acceptance criteria for permanent contact (greater than 30 days) with mucosal membrane and breached/compromised surfaces.
Performance Testing:	AMT conducted various performance tests on the components contained within the Low Profile Balloon Feeding Device. Testing found that all components and materials met or exceeded design specifications established by AMT. Bench tests have been carried out on samples of the Low Profile Balloon Feeding Device. The tests carried out included: • Stoma Pullout • Minimum Overmold Bond Strength • Fill Valve Blow Out • Fill Valve Pullout • Fill Valve Cycle Test • Balloon Assembly Bond Peel/Tear Strength • Balloon Burst • Assembled Balloon Size • Interlock Pullout • Leak Test

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	• Balloon Concentricity Ratio • Tubing Tensile Testing • Flow Rate • Balloon Volume Maintenance • Balloon Integrity • Balloon Integrity in Simulated Gastric Fluid Testing
Conclusion:	The Low Profile Balloon Feeding Device is substantially equivalent to the predicate device cleared under K122653 in intended use, design, biocompatibility, performance, and principles of operation.