October 6, 2017

Applied Medical Technology, Inc.
Shraddha Saini
Regulatory Affairs Specialist
8006 Katherine Boulevard
Brecksville, OH 44141

Re: K170319
Trade/Device Name: Low Profile Non-Balloon Feeding Device
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KNT
Dated: September 12, 2017
Received: September 13, 2017

Dear Shraddha Saini:

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 (DICE) 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 (DICE) 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,

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)*
K170319

Device Name
Low Profile Non-Balloon Feeding Device.

Indications for Use *(Describe)*
The Low Profile Non-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.

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

Low Profile Non-Balloon Feeding Device

Date Prepared:	September 12, 2017
Submitter:	Applied Medical Technology, Inc. 8006 Katherine Boulevard Brecksville, OH 44141 Phone: 440-717-4000 Fax: 440-717-4200 Contact Person: Shraddha Saini – Regulatory Affairs Specialist Email: Shraddha.Saini@appliedmedical.net
Device Information:	Trade Name: Low Profile Non-Balloon Feeding Device Common Name: Gastrointestinal Feeding Tubes Classification Name: Gastrointestinal Tube and Accessories (21 CFR 876.5980) Product Code: KNT Regulatory Class: II Review Panel: Gastroenterology and Urology
Predicate Device:	AMT Button Replacement Gastrostomy Device (K980305) Capsule Monarch Trans shaping Gastrostomy Tube (K043027)
Intended Use:	The Low Profile Non-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.
Device Description:	The Low Profile Non-Balloon Feeding Device is used to provide nutrition, medication, and decompression access into the stomach through a secured (initial placement) or formed (replacement) stoma. The device may be placed using one of two insertion methods including an 'obturator' insertion method and a 'capsule' insertion method. Capsule Insertion Method: The internal bolster of the device is encased by water dissolvable capsule. The capsule technology provides a low-profile option that is delivered by lubricating the capsule with lubricant, inserting the device through the stoma site, and pulling on a pull tab that pulls a suture through the capsule and deploys the internal dome. Once the capsule is deployed, the internal dome returns to its uncompressed shape and the device is held in place. Obturator Insertion Method: A T-Handle and ratcheting obturator rod (Snap Arm Assembly) is used to extend the internal dome, decreasing the outer profile of the dome. When the dome is fully elongated, the internal dome maintains a

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	narrow profile that can easily be inserted into the stoma site with proper lubrication. Once inserted into the stoma site, the ratcheting rod and T-handle are removed and device is held in place by the internal bolster. Once placed, both devices provide access to nutrition, medication, and decompression into the stomach via a Mini ONE® feeding port. Both devices are identical after placement regardless of the insertion method chosen. Removal of feeding device can be performed by using a removal tool assembly (Snap Arm and T-handle with removal tool reinforcer). Removal is done by elongating the internal bolster to reduce the outer diameter of the dome, providing for an easier removal process. The Low Profile Non-Balloon Feeding Device will be offered in several different diameters including14 Fr, 18 Fr, 20 Fr, and 24 Fr and will be available in stoma lengths ranging from 1.0 cm to 4.4 cm.
Technological Characteristics:	The Low Profile Non-Balloon Feeding Device is provided sterile for single use only. The molded body of the Non-Balloon feeding device is made of medical silicone. The Low Profile Non-Balloon Feeding Device consists of an external bolster, feeding catheter, and internal retention bolster similar to the predicate devices. The external bolster consists of a feeding port for access to the stomach through the tubing of the device and a strap with a plug to close the feeding port while not in use. In addition, an anti-reflux valve is included in the feeding port area to prevent backflow of stomach contents while not in use. The feeding catheter is inserted into the stomach through a stoma and is held in place with the internal retention bolster. There are two different insertion methods for the proposed device, the 'capsule' and the 'obturator' method. The 'capsule' version includes a tapered capsule enclosing the internal bolster at one end that allows ease of insertion and an obturator rod is pre-loaded in to the shaft prior to use. The 'obturator' version uses a T-Handle and snap arm assembly for controlled insertion and elongation through the device shaft. The Low Profile Non-Balloon Feeding Device and the predicate devices are provided in a number of sizes to accommodate different stoma diameters and lengths. Design Differences: **Method of Insertion:** The proposed devices provides two different methods of insertion ('Capsule' or 'Obturator'), whereas the predicate devices are only provided with a single method of insertion. The Capsule Monarch Trans shaping Gastrostomy Tube uses the same Capsule technology of the proposed device but does not offer a Snap arm assembly and T-handle method for insertion. The AMT Button Replacement Gastrostomy Device uses an insertion rod to insert the device, but does not offer the level of control and repeatability for insertion that the proposed device offers with the Snap arm assembly and T-handle components. Both predicate devices don't use removal tools, allowing the proposed device to have a more comfortable means of removal by avoiding a necessary retraction removal. **Interlock and Anti-Reflux Valve:** The proposed device incorporates an interlock for its feeding port, whereas the predicate devices do not have interlocks. The proposed device incorporates an anti-reflux valve that is located along the proximal end of the tubing along the external bolster. The Capsule Monarch Trans shaping Gastrostomy Tube does not include an anti- reflux valve and relies only on external plugs to prevent leakage. The AMT Button Replacement Gastrostomy Device includes an anti-reflux valve along the distal

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	the proposed device. The overall functionality and safety of the proposed Low Profile Non Balloon Feeding Device remains substantially equivalent to the predicate devices.
Biocompatibility Testing:	The patient contacting components of the Low Profile Non-Balloon Feeding Device are in contact with mucosal membrane and/or breached/compromised surfaces for prolonged or permanent exposure. No additional biocompatibility testing was conducted because the patient-contacting components in the final finished device are identical to those in previously marketed devices (in terms of formulation, processing, sterilization, geometry, nature of use, and duration of exposure) and no chemicals were added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents).
Performance Testing:	AMT conducted various performance tests on the components contained within the Low Profile Non-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 Non-Balloon Feeding Device. The tests carried out included: • Stoma Pullout Force • Tip Poke-Through Force • Snap Arm Body to Rod Attachment Force • Snap Arm to T-Handle Snap Engagement Force • T-Handle Tooth Shear Strength • Interlock Pullout • Time to Capsule Rupture • Suture Deployment Force • Ripcord Tensile Strength • Pull Tab-to-Suture Bond Strength • Liquid Leakage Test • Flow Rate Test (Water and Viscous Fluid) • Tube Tensile Test • Obturator Bond Strength Test • Duckbill Flow and Backflow Test • Obturator Poke-Through Evaluation • Obturator Push-Through Force Test
Conclusion:	The Low Profile Non-Balloon Feeding Device is substantially equivalent to the predicate devices cleared under K980305 and K043027 in intended use, design, biocompatibility, performance, and principles of operation.