October 29, 2020

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

Re: K202539
Trade/Device Name: Nutriglide™ Nasal Feeding Tube
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: August 31, 2020
Received: September 2, 2020

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/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 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 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,

For 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)*
K202539

Device Name
NutriGlide™ Nasal Feeding Tube

Indications for Use *(Describe)*
The NutriGlide™ Nasal Feeding Tube is indicated for the administration of nutrition, fluids, and medications in neonatal, pediatric, and adult patients.

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

Nasal Feeding Tube

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 Specialist
Email: joy.tubero@appliedmedical.net
Date Prepared: August 31, 2020

II. DEVICE INFORMATION:

Trade/Device Name: Nutriglide™ Nasal Feeding Tube
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 Devices:

- **K821906** Corpak enteric feeding tube w/guide tip; Corpak Medsystems
- **K831328** Neonatal Nasogastric feeding tube, Corpak Enteric Feeding Tube w/Guide Tip; Corpak Medsystems

****These predicate devices have not been subject to design-related recalls.**

IV. INDICATIONS FOR USE:

The Nutriglide™ Nasal Feeding Tube is indicated for the administration of nutrition, medication, and fluids to neonatal, pediatric, and adult patients.

V. DEVICE DESCRIPTION:

The Nutriglide™ Nasal Feeding Tube is a nasal feeding tube available in both sterile and non-sterile ENFit® and legacy configurations featuring a y-port, widening lumen diameter, dissolvable tube tip, and optional stylet with water activated lubricous coating.

The device is identical between the ENFit® and legacy configurations but for the y-port which will feature either ENFit® adapters or the legacy ports. Both configurations feature tubing with a unique taper design where the lumen gradually increases from the proximal end (external) to the distal opening (indwelling). This design creates a tube that is smaller near the external y-port and gradually

increases to its largest diameter at the distal tip opening where the nutrition/medication exists into the patient's stomach or small intestine.

The lubricious dissolvable tip offers increased comfort during placement on the various configurations of both the ENFit® and legacy devices, and then once dissolved it reveals the entire rounded distal opening of the tube, allowing for maximum flow during feeding.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE:

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

	Subject Device:	**Predicate:** **K821906**	**Predicate:** **K831328**
Device Class and Product Code:	Class II; KNT	Class II; KNT	Class II; KNT
	Substantial Equivalence:	Same	
Sterilization:	• Sterile (Ethylene Oxide), single use only. • Non-sterile, single use only	• Sterile (Ethylene Oxide), single use only. • Non-sterile, single use only	• Sterile (Ethylene Oxide), single use only. • Non-sterile, single use only
	Substantial Equivalence:	Same	
Prescription	Single use: Prescription Only.	Single use: Prescription Only.	Single use: Prescription Only.
	Substantial Equivalence:	Same	
Indications for Use:	Intended for use for the administration of nutrition, fluids, and medications in neonatal, pediatric, and adult patients.	Intended for use for the administration of nutrition, fluids, and medications in neonatal, pediatric, and adult patients.	Intended for use for the administration of nutrition, fluids, and medications in neonatal, pediatric, and adult patients.
	Substantial Equivalence:	Same	
Intended Use:	Deliver intermittent or continuous feeding via the nasogastric or nasoenteric route.	Deliver intermittent or continuous feeding via the nasogastric or nasoenteric route.	Deliver intermittent or continuous feeding via the nasogastric or nasoenteric route.
	Substantial Equivalence:	Same	

TABLE 5.1- TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT DEVICE AND THE PREDICATE DEVICES			
	Subject Device:	**Predicate:** **K821906**	**Predicate:** **K831328**
Principles of Operation	•Manually operated •Non-powered	•Manually operated •Non-powered	•Manually operated •Non-powered
	Substantial Equivalence:	Same	
Major Design Characteristics	• Tapered tubing • External y-port for administering feed/medication • ENFit® and legacy configurations to meet user demand	• Straight tubing • External y-port for administering feed/medication • ENFit® and legacy configurations to meet user demand	• Straight tubing • External y-port for administering feed/medication • ENFit® and legacy configurations to meet user demand.
	Substantial Equivalence:	Similar	

As outlined above, minor differences exist among the nasal tube and the predicate devices. These differences include:

- Tapered tubing: The subject device configurations feature tubing that is tapered to increase in diameter from the proximal to the distal end of the device whereas the predicate device configurations are straight tubes.
- Dissolvable tip: Configurations of the subject device feature a tip that dissolves completely, exposing the entire lumen of the distal portion of the tubing, whereas the configurations of the predicates feature a permanent tip component with exit holes.

These design differences between the Nutriglide™ Nasal Feeding Tube (subject device), and the predicates (K821906 and K831328) do not raise different questions of safety and/or effectiveness from the predicate devices. The intended use and indications for use remain the identical between the Nutriglide™ Nasal Feeding Tube and the predicate devices.

VII. PERFORMANCE DATA:

A. Biocompatibility Testing:

Following a well-documented biological evaluation plan, biocompatibility testing results demonstrate that the device is in compliance with ISO 10993-1- Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing and applicable endpoints of evaluation.

- ISO 10993-1 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
  – 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
- USP <151> Pyrogen Test (USP Rabbit Test)

B. Performance Testing:

AMT conducted various performance tests on the components contained within the nasal tube. Testing found that all components and materials met or exceeded design specifications established by AMT and performed comparably to the predicate.

1. Sterilization

The Nasal tube is provided both in non-sterile and sterile (ethylene oxide) configurations. Testing has been completed to evaluate the sterilization process for the devices provided sterile. The testing is outlined below:

- Testing per ANSI/AAMI/ISO 11135:
  - Sterilization process validation
- Testing per ISO 10993-7:
  - Part 7: Ethylene Oxide Sterilization Residuals.

The sterile configurations of the subject device are ethylene oxide sterilized, and have been validated to confirm a Sterility Assurance Level (SAL) of 10^{-6}. The sterilization processing complies with the standards.

2. Shelf Life

The sterilized packaging for the subject device was tested in accordance with the following:

- Testing in accordance with ASTM F1980-16:
  - Accelerated aging of sterile barrier systems
- Testing per ISO 11607:
  - Packaging system performance testing
- Testing per ISTA 3A:

- Packaged products for parcel delivery system shipments

Testing of the sterile barrier system has indicated that the packaging for the subject device complies with the standards.

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. The tests carried out included:

- Testing per ASTM F2528
  - Standard Test Methods for Enteral Feeding Devices with a Retention Balloon
- Testing per EN 1618:1997
  - Catheters other than intravascular catheters- Test methods for common properties
- Testing per EN1615:2000
  - Enteral Feeding catheters and Enteral Giving Sets for Single Use and their Connectors- Design and Testing
- Testing per ISO 80369-3
  - Small-bore connectors for liquids and gases in healthcare applications- Part 3: Connectors for enteral applications
- Bench testing according to AMT specifications:
  - Kink Distance
  - Clog Formation
  - Clog Removal
  - Tip Dissolution
  - Lubricious Coating
  - Component Attachment strength
  - Component integrity testing

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

C. Animal Study: Animal testing was NOT performed.

D. Clinical Study: Clinical testing was NOT performed.

VIII. CONCLUSION:

The Nutriglide™ Nasal Feeding Tube can be found substantially equivalent to the predicate devices cleared under K821906 and K831328 in intended use, performance, and principles of operation. The minor design differences between the subject and the legally marketed predicates do not raise different questions of safety and/or efficacy, and the information submitted in the application demonstrates that the subject devices are at least as safe and effective as the current legally marketed devices.