November 22, 2024

Gravitas Medical, Inc.
% Lucie Dalet
Principal
Rqm+
2251 San Diego Ave.
Suite B-257
San Diego, California 92110

Re: K241169
Trade/Device Name: Entarik NI Feeding Tube System
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube (And Accessories)
Regulatory Class: Class II
Product Code: KNT, FPD
Dated: October 16, 2024
Received: October 16, 2024

Dear Lucie Dalet:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Anthony Lee -S

Anthony Lee, 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241169

Device Name
Entarik NI Feeding Tube System

Indications for Use *(Describe)*
Entarik NI Feeding Tubes (FTs) are intended for the administration of nutrition, fluids and medications by the nasoenteric or orogastric route for neonatal patients who have an intact gastrointestinal tract but are physically unable to manage nutritional intake through normal mastication and deglutition.

The Entarik NI Feeding Tube System (Entarik NI System) is designed to aid, in conjunction with institutional protocols, qualified operators in the placement of the Entarik NI Feeding Tube(FT) into the stomach of neonatal patients requiring enteral feeding. The Entarik FTs are equipped with sensors designed to provide information about the location of the tube tip relative to the stomach, thus assisting in reducing the incidence of misplacement during first positioning. The Entarik NI FTs are provided sterile.

The Entarik NI System also monitors the feeding tube position continuously during the course of feeding and automatically and in real time alerts of tube migration.

The Entarik NI System provides continuous monitoring of gastric and esophageal temperature. The Entarik device can be used solely for the purpose of monitoring gastric and esophageal temperature in situations where invasive monitoring is indicated.

The Entarik NI system is intended to record, store, view and analyze impedance in the pharynx, esophagus and stomach.

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.

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:

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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."

510(k) SUMMARY
K241169

DATE PREPARED
November 21, 2024

MANUFACTURER AND 510(k) OWNER
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DEVICE INFORMATION

Proprietary Name/Trade Name:	Entarik NI Feeding Tube System
Common Name:	Tubes, Gastrointestinal (And Accessories)
Regulation Number:	21 CFR 876.5980
Class:	Class II
Product Codes	KNT, FPD
Premarket Review:	OHT 3 / DHT3A
Review Panel:	Gastroenterology/Urology

PREDICATE DEVICE IDENTIFICATION
The Entarik NI Feeding Tube System is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K230206	Entarik Feeding Tube System / Gravitas Medical Inc.	✓
K202539	Nutriglide™ Nasal Feeding Tube / Applied Medical Technology, Inc.	
K131590	InnerSense Esophageal Temperature Probe, Feeding Tube / Philips Medical Systems	

The predicate devices have not been subject to a design-related recall.

GRAVITAS MEDICAL
Enteral Nutrition Intelligence

DEVICE DESCRIPTION

The Entarik NI Feeding Tube System (Entarik NI System) consists of the Entarik NI Feeding Tube (disposable) and the Entarik NI Monitor (reusable) with Power Supply. The Entarik NI System is designed for enteral feeding and to aid in the placement of the Entarik NI Enteral Feeding Tube into the stomach of neonatal patients requiring enteral feeding. The Entarik NI System also continuously monitors feeding tube position, gastric and esophageal temperature, and gastrointestinal impedance and reflux. The feeding tubes are single use devices intended for prolonged use (less than 30 days). The Entarik NI Feeding Tubes are provided sterile.

INDICATIONS FOR USE

Entarik NI Feeding Tubes (FTs) are intended for the administration of nutrition, fluids and medications by the nasoenteric or orogastric route for neonatal patients who have an intact gastrointestinal tract but are physically unable to manage nutritional intake through normal mastication and deglutition.

The Entarik NI Feeding Tube System (Entarik NI System) is designed to aid, in conjunction with institutional protocols, qualified operators in the placement of the Entarik NI Feeding Tube (FT) into the stomach of neonatal patients requiring enteral feeding. The Entarik FTs are equipped with sensors designed to provide information about the location of the tube tip relative to the stomach, thus assisting in reducing the incidence of misplacement during first positioning. The Entarik NI FTs are provided sterile.

The Entarik NI System also monitors the feeding tube position continuously during the course of feeding and automatically and in real time alerts of tube migration.

The Entarik NI System provides continuous monitoring of gastric and esophageal temperature. The Entarik device can be used solely for the purpose of monitoring gastric and esophageal temperature in situations where invasive monitoring is indicated.

The Entarik NI System is intended to record, store, view and analyze impedance in the pharynx, esophagus and stomach.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Gravitas Medical, Inc. believes that the Entarik NI Feeding Tube System is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has the same intended use as the primary predicate cleared in K230206 and similar Indications for Use to the primary and secondary predicates. The subject device has a similar design and uses identical materials as the primary predicate device cleared in K230206. The main differences with the primary predicate device include changes in intended patient population, modifications of the Feeding Tubes, and software modifications. The subject device is intended for use in neonates whereas the primary predicate device is intended for adults. As a result, changes were made to the Feeding Tubes dimensions and electrodes number and spacing to adapt the device to the anatomy of neonates, similar to the predicate device cleared in

K202539 for neonatal, pediatric, and adult patients. Software modifications include changes in calculation methods to adjust to the anatomical specificities of neonates, and the addition of temperature and impedance monitoring functionalities, which are similar to the functionalities of the predicate device cleared in K131590, All these technological characteristics have undergone testing to ensure the device is as safe and effective as the predicates.

SUMMARY OF NON-CLINICAL TESTING

The following tests were performed to demonstrate substantial equivalence based on current industry standards.

Sterilization

Sterilization validation was performed in accordance with the following standards:

- Sterilization validation per ISO 11135-1 *Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices*
- Ethylene oxide sterilization residuals per ISO 10993-7 *Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals*

Biocompatibility

Biocompatibility evaluation was conducted according to ISO 10993-1:2018 *Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process* and FDA's Biocompatibility Guidance. Since the materials and manufacturing processes of the subject device are identical to the primary predicate device, testing conducted on the predicate was leveraged to demonstrate biocompatibility of the subject device. Leveraged testing included:

- Cytotoxicity Study Using the ISO Elution Method
- ISO Intracutaneous Irritation Test
- ISO Maximization Sensitization Test
- ISO Acute Systemic Toxicity Study
- ISO Sub-acute Systemic Toxicity Study
- ISO Intramuscular Implantation Test
- ISO Material Mediated Pyrogenicity

Software

Software verification and validation testing was performed per IEC 62304:2015 *Medical device software – Software life cycle processes* to demonstrate safety and performance based on current industry standards.

Electrical, Mechanical, and Thermal Safety, and Electromagnetic Compatibility

The Entarik NI Feeding Tube System has been designed to comply with the following standards covering electrical, mechanical, and thermal safety:

- AAMI/ANSI ES60601-1 *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*.

- IEC 60601-1-6 *Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability*
- IEC 60601-1-8 *Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
- IEC 80601-2-49 *Medical electrical equipment Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment*
- ISO 80601-2-56 *Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement*
- *IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*

Performance Testing

The following bench tests were performed on the Entarik NI Feeding Tube and Monitor (where applicable):

- Dimensional Verification
- Impedance and Temperature Accuracy and Sensing Rate
- Insertion and Withdrawal
- Flow and Pressure
- Buckle and Kink
- Tensile Integrity
- Viscous Feed Testing
- Radiopacity
- Product and Label Durability

SUMMARY OF CLINICAL TESTING

Two clinical studies were conducted with the subject device.

- Observational study for algorithm training and optimization in 16 subjects ranging from 30 to 39 weeks of gestational age. The Entarik Feeding Tube (FT) was placed in all participants while connected to the Entarik NI Monitor. The Entarik NI Monitor did not provide any placement guidance or verification. It collected impedance and temperature data silently that was used to train and optimize the placement and monitoring algorithm for this population of patients.
- Validation study conducted on 11 subjects ranging from 32 to 43 weeks of gestational age to assess the efficacy and safety of the system on the neonatal population. The Entarik FT was placed under the guidance of the Entarik NI Monitor, and placement was confirmed per institutional standard of care. The Entarik NI Monitor stayed connected to the Entarik FT for a target of 72 hours in each patient to continuously monitor tip location, as well as provide nutrition and medication to the patients. The study demonstrated that the Entarik NI System was safe and effective in all eleven neonatal participants to aid qualified operators in the placement of the Entarik FT into the stomach

of patients, and monitor the feeding tube position continuously and automatically and in real-time alert of tube migration.

CONCLUSION

The Entarik NI Feeding Tube System is substantially equivalent to the primary predicate device cleared in K230206, with the changes being the intended patient population, dimensions changes of the Feeding Tubes, and the addition of temperature and impedance monitoring. The intended patient population is similar to the secondary predicate cleared in K202539 and the added functionalities are substantially equivalent to the secondary predicate cleared in K131590. Based on the testing performed, including software verification and validation testing, electrical, mechanical, and thermal safety testing, electromagnetic compatibility (EMC) testing, bench performance testing, and clinical testing, it can be concluded that the subject device does not raise different questions of safety or effectiveness compared to the predicate devices. The intended use, patient population, technological characteristics, and performance characteristics of the subject device are considered substantially equivalent to the predicate devices.