March 24, 2023

Gravitas Medical, Inc.
Saheel Sutaria
Chief Executive Officer
101 Mississippi St
San Francisco, CA 94107

Re: K230206
Trade/Device Name: Entarik Feeding Tube System; Entarik Feeding Tube
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube And Accessories
Regulatory Class: Class II
Product Code: KNT
Dated: January 24, 2023
Received: January 25, 2023

Dear Saheel Sutaria:

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,

Shanil P. Haugen -S

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)*
K230206

Device Name
Entarik™ Feeding Tube

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

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:

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."

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)*
K230206

Device Name
Entarik™ Feeding Tube System

Indications for Use *(Describe)*
The Entarik Feeding Tube System is designed to aid, in conjunction with institutional protocols, qualified operators in the placement of the Entarik Feeding Tube (Entarik FT) into the stomach of patients requiring enteral feeding. The Entarik FT is 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 Monitor also monitors the feeding tube position continuously during the course of feeding and automatically and in real-time alerts of tube migration.

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)

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510(k) Summary (21 CFR § 807.92(c))

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number:	K230206
Date Prepared:	January 24, 2023
Applicant Information:	Gravitas Medical, Inc 101 Mississippi St. San Francisco, CA 94107
Contact:	Saheel Sutaria
Office Number:	415-926-8616
Email:	ssutaria@gravitasmedinc.com

Device Information:

Trade/Device Name:	Entarik™ Feeding Tube System Entarik™ Feeding Tube
Common Name:	Feeding Tube and Accessories
Regulation Number:	21 CFR 870.5980
Regulation Name:	Gastrointestinal Tube and Accessories
Regulatory Class:	Class II
Product Code:	KNT
Panel:	Gastrointestinal and Urology Devices
Predicate Device:	smARTrack™ Feeding Tube System (K142327)

Device Description

The Entarik Feeding Tube System (Entarik System) consists of the Entarik Enteral Feeding Tube and the Entarik Monitor. The Entarik Feeding Tube is a nasogastric feeding tube with a single lumen for the administration of nutrition, fluids and medications. The Entarik Feeding Tube includes impedance and temperature sensors embedded within the tube, with wires located in the wall of the feeding tube. The Entarik Monitor is a portable electronic device that serves to measure and record impedance and temperature data from the sensors on the Feeding Tube and provides information to the operator to aid in initial placement and monitoring of feeding tube position.

Indications for Use

Entarik Feeding Tube

The Entarik Feeding Tube is intended for the administration of nutrition, fluids and medications by the nasoenteric route for patients who have an intact gastrointestinal tract but are physically unable to manage nutritional intake through normal mastication and deglutition.

Entarik Feeding Tube System

The Entarik Feeding Tube System is designed to aid, in conjunction with institutional protocols, qualified operators in the placement of the Entarik Enteral Feeding Tube (Entarik FT) into the stomach of patients requiring enteral feeding. The Entarik FT is 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 Monitor also monitors the feeding tube position continuously during the course of feeding and automatically and in real-time alerts of tube migration.

Functional and Technological Comparison

The Entarik Feeding Tube System and smARTrack Feeding Tube System are both comprised of an electronic console which holds the system software and serves as the guiding interface to the user during initial tube placement as well as during ongoing use. The consoles both provide an alert when the system senses that the tube has moved out of position during ongoing use. Both the Entarik and smARTrack Feeding Tubes incorporate wired impedance sensors which transmit real-time information to the console regarding the feeding tube location.

There are some technological differences between the Entarik and smARTrack Feeding Tube Systems. The smARTrack device automatically stops feeding using a motorized mechanism in the event of tube dislodgement, whereas the Entarik device does not have that feature. The Entarik Feeding Tube System has an alert to notify the user in event of tube dislodgement. In addition to impedance sensors, the Entarik Feeding Tubes also incorporate temperature sensors for additional information. The number, size, and location of the sensors, and the algorithms to determine tip location, are different between the Entarik and smARTrack systems.

To address the technological differences, the Entarik Feeding Tube System has undergone bench, pre-clinical, and clinical testing to ensure it functions correctly and achieves proper placement as well as correctly identifies tube malposition during the course of use. The performance data is provided in various sections of this submission. The Entarik System has successfully demonstrated its ability to guide the user in correct feeding tube placement. The system also correctly identifies tube movement. In the clinical study which was conducted, tube placement was initially verified with the Entarik System and a confirmatory X-Ray ("gold standard" placement verification) was performed. In all cases the Entarik System successfully guided the user to ensure correct placement was achieved. The available performance data supports the safety and effectiveness profile of the system and negates the technological differences between the Entarik System and the predicate device.

The Entarik feeding tubes are available in 8 and 12 Fr. The smARTrack feeding tube is available in 14Fr only. There are many FDA cleared feeding tubes which are available in various sizes ranging from 6 to 21 Fr. Therefore, this difference in tube diameter does not raise any new safety or effectiveness concerns as both devices are intended to be used in adult patients. Furthermore, biocompatibility tests were also performed to ensure the tubes are safe for use.

Performance Data

Below is a list of the tests that have been performed and successfully completed for the Entarik Feeding Tube System.

Biocompatibility:

The biocompatibility evaluation for the Entarik System Feeding Tube was conducted in accordance with the FDA Guidance "Use of ISO 10993 –1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" (June 2016) and International Standard ISO 10993-1:2018 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The Entarik Enteral Feeding Tube (FT) is considered to fall under the guidelines for a surface contacting device with direct mucosal tissue contact for a prolonged patient contact duration (>24 hours to 30 days) per the ISO/FDA guidelines and an actual patient exposure duration of less than ≤30 days in the clinical application.

The battery of testing included the following tests:

- 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

Electrical safety and electromagnetic compatibility (EMC):

The system was tested and found to comply with IEC 60601-1:2005/EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance 3rd Ed and IEC 60601-1-2:2007 Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests.

Software Verification and Validation Testing:

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", (issued May 11, 2005). The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software could result in minor injury to the patient.

Bench:

Bench testing performed on the Entarik Feeding Tube included 1) Gastric Soak and Preconditioning, 2) Dimensional, 3) Impedance and Temperature Accuracy and Sensing Rate, 4) Insertion and Withdrawal, 5) Flow and Pressure, 6) Buckle and Kink, 7) Tensile Integrity, 8) Simulated Use, 9) Radiopacity, 10) Product and Label Durability, and 11) Usability. These bench performance studies confirm that the device performed as intended per the product specifications and also demonstrated that the Entarik Feeding Tube System is substantially equivalent to the smARTrack Feeding Tube System predicate device.

Human Factors:

The Entarik Feeding Tube System was evaluated by fifteen (15) intended users in a simulated clinical setting. This testing was conducted pursuant to the applicable requirements of FDA's Guidance Document titled "Applying Human Factors and Usability Engineering to Medical Devices (issued February 3, 2016)." For this evaluation, the users were trained by Gravitas personnel. Post training, users were provided with the Entarik Feeding Tube System and the proposed Instructions for Use. Tasks were assessed through observation during simulated use and through user knowledge assessments about the device's labeling and procedure steps that were not amendable to simulated use testing. Additionally, the test subjects completed a survey. The human factors assessment demonstrated that the device labeling and training provided to the intended users allowed for the proper use of the Entarik Feeding Tube System in its intended use environment. Further, this assessment confirmed that all identified risks were considered acceptable and that no new risks were identified.

Animal:

The Entarik Monitor contains an algorithm to determine if the tip of the feeding tube is in the respiratory tract. A study was conducted to develop and validate the algorithm in a porcine model. After induction of general anesthesia and placement of an endotracheal tube, the feeding tube was intentionally placed in the respiratory tract of eight pigs at various depths of insertion, and the algorithm was successful in detecting respirations in all eight pigs and at all depths of insertion.

Clinical:

Clinical studies were conducted to develop an algorithm to guide feeding tube placement into the stomach. A feasibility validation study was conducted in 10 healthy volunteers to assess the functionality and safety of the system. Tube insertions in all subjects were successful with no major issues reported. The entire procedure was well tolerated by the subjects. No unexpected adverse events were reported. Most patients that undergo feeding tube insertion experience some pain and discomfort and therefore none of the feedback that was received from the healthy volunteers was unexpected. It should be noted that the main target population for the system would be unconscious or anesthetized patients for whom minor pain and discomfort would be negligible. Furthermore, according to the patients' subjective feedback, throughout the procedure, no severe pain or discomfort was recorded. The convenience of the feeding tube insertion was assessed via questionnaires completed by the clinical staff. Correct placement of the tube was verified via X-Ray. No incorrect placements occurred while using the feeding tube.

Conclusion:

The Entarik Feeding Tube System has a similar intended use as the smARTrack predicate device. The Entarik Feeding Tube System is similar in technological and performance characteristics to the smARTrack predicate. The minor technological differences do not raise any new safety and effectiveness risks or concerns. It can be concluded that the Entarik Feeding Tube System is as safe and effective as the predicate device for the intended use, and is substantially equivalent.