July 3, 2024

Alimetry Ltd.
℅ Janice Hogan
Regulatory Counsel
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19103

Re: K240946
Trade/Device Name: Gastric Alimetry
Regulation Number: 21 CFR 876.1735
Regulation Name: Electrogastrography System
Regulatory Class: Class II
Product Code: MYE
Dated: April 5, 2024
Received: April 5, 2024

Dear Janice Hogan:

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.

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,

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240946

Device Name

Gastric Alimetry

Indications for Use *(Describe)*

The Gastric Alimetry System is intended to record, store, view and process gastric myoelectrical activity as an aid in the diagnosis of various gastric disorders.

The Gastric Alimetry System is indicated for patients 12 years and older.

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."

510(K) SUMMARY
Alimetry's Gastric Alimetry

Submitter

Alimetry Ltd.

Address: 70 Symonds St.
Grafton
Auckland 1010
New Zealand

Phone: +64 27 622 2306

Contact Person: Yaara Yarmut, Chief Regulatory Officer.

Date Prepared: April 5, 2024

Name of Device: Gastric Alimetry

Common or Usual Name: Gastric Alimetry System

Classification Name: Electrogastrography system, 21 CFR 876.1735

Regulatory Class: Class II

Product Code: MYE

Predicate Devices

Trade Name: Gastric Alimetry (K232925) (primary predicate)

Manufacturer: Alimetry Ltd.

Device Description

The Gastric Alimetry System is an electrogastrography (EGG) device, used for non-invasively measuring the myoelectrical activity of the stomach at the surface of the abdomen. The Gastric Alimetry System is intended to record, store, view and process gastric myoelectrical activity as an aid in the diagnosis of various gastric disorders.

The device is used to acquire and digitize gastric myoelectrical data and movement artifacts using the Alimetry Reader connected to a single use Gastric Alimetry Array which includes electrodes on an adhesive patch used for recording the myoelectrical data from the skin surface. The Gastric Alimetry App runs on an iPad mini and is used to set up the device and capture patient-reported symptom data. The Gastric Alimetry Report is provided to the clinicians at the end of the test and includes myoelectrical signal data for manual analysis, together with computed data summaries and plots. A Supplementary Report is also routinely available to clinicians that includes signal data from all 64 channels on the array. The Alimetry Cloud acts as a secure website portal for physicians to access Gastric Alimetry Reports. The Gastric Alimetry Dock (Accessory) is used to guide

alignment of the Array and Reader during the setup procedure and charge the Reader.

The Gastric Alimetry System is non-invasive and used in healthcare facilities.

The device is mostly unchanged compared to the previously cleared Gastric Alimetry System, apart for the following modifications:

Labelling:
- Inclusion of adolescent patient population age 12 years and over in the indications for use statement and associated labeling.
- Inclusion of a report interpretation guide and phenotyping patterns diagram to provide information to the clinician.

Modification to the report:
- Inclusion of the normative reference intervals
- Updated Gut-Brain Wellbeing Survey .
- Adding a Gut-Brain Wellbeing Total Score
- Updated Amplitude plot to BMI-Adjusted Amplitude' plot

Additional minor updates were made to the cloud, algorithm, app, labels and packaging.

Intended Use / Indications for Use

The Gastric Alimetry System is intended to record, store, view and process gastric myoelectrical activity as an aid in the diagnosis of various gastric disorders.

The Gastric Alimetry System is indicated for use in patients 12 years and older**.**

The modified Gastric Alimetry System that is the subject of this submission is "intended to record, store, view and process gastric myoelectrical activity as an aid in the diagnosis of various gastric disorders". There are no changes to the intended use in comparison to the predicate Gastric Alimetry System (K232925) which has an identical intended use, being "intended to record, store, view and process gastric myoelectrical activity as an aid in the diagnosis of various gastric disorders".

The modified Gastric Alimetry System is indicated for patients 12 years and older. This is a modification from the predicate Gastric Alimetry System which is indicated for patients 18 years and older. Systematic review of the extensive general medical literature, together with real-world and structured research evaluations specific to the Gastric Alimetry System, show comparable device performance in adolescents with no new questions of safety and efficacy.

Technological Characteristics / Substantial Equivalence

At a high level, the subject and predicate devices are based on the same technological elements: Both the modified Gastric Alimetry system and the Gastric Alimetry system use identical hardware (Alimetry Reader for recording the myoelectrical activity from the patient), identical accessories (Gastric Alimetry Array for recording the myoelectrical activity from the patient and the Gastric Alimetry Dock for device setup and charging), identical dedicated tablet device (i.e. a commercial off-the-shelf iPad mini that is supplied with the system and running on a mobile device management system) and equivalent secure Alimetry Cloud.

The following technological differences exist between the subject and predicate devices:

- Updating the Amplitude plot to a BMI-adjusted Amplitude plot.
- Updating the spectral analysis section to include normative ranges.
- Updating the Gut-Brain Wellbeing survey responses presentation and adding a total score.

A table comparing the key features of the subject and predicate devices is provided below.

	Gastric Alimetry System	**Gastric Alimetry System (predicate)**	**Discussion**
Intended Use	To record, store, view and process gastric myoelectrical activity as an aid to the diagnosis of various gastric disorders.	To record, store, view and process gastric myoelectrical activity as an aid to the diagnosis of various gastric disorders.	Same as the predicate.
Indications for Use	Patients 12 years and older	Patients 18 years and older	Different. The subject device is indicated for patients 12 years and older whereas the predicate is indicated for patients 18 years and older. This difference in use population does not raise different questions of safety or effectiveness. See discussion above the indications for use.
User Population	Medical professionals to set up and use the system Patients 12 years and older Specialist GI physicians	Medical professionals to set up and use the system Patients 18 years and older Specialist GI physicians	Different. See above.
Technological Characteristics			
Setup and Charging Dock	Gastric Alimetry Dock for charging and user convenience	Gastric Alimetry Dock for charging and user convenience	Same as the predicate.
Electrodes	Disposable; same components as ECG electrodes. Peel-and-stick patch.	Disposable; same components as ECG electrodes. Peel-and-stick patch.	Same as the predicate.
Weight of device on patient	225 grams - Reader and Array	225 grams - Reader and Array	Same as the predicate.

	Gastric Alimetry System	Gastric Alimetry System (predicate)	Discussion
Sampling Frequency	raw sampling: 250 Hz logging: 4 Hz	raw sampling: 250 Hz logging: 4 Hz	Same as the predicate.
Low Frequency Range	DC	DC	Same as the predicate.
High frequency range	2 Hz	2 Hz	Same as the predicate.
Number of channels	64 (+2 reference)	64 (+2 reference)	Same as the predicate.
Electrode to recorder interface	Reader located on the Array and directly connected to it.	Reader located on the Array and directly connected to it.	Same as the predicate.
Screen	Dedicated tablet for system operation	Dedicated tablet for system operation	Same as the predicate.
Motion Sensor	Accelerometer	Accelerometer	Same as the predicate.
Power Source	Battery powered	Battery powered	Same as the predicate.
Reporting Features			
Visualization of myoelectrical waveforms	Yes, all channels.	Yes, all channels.	Same as the predicate.
Automated Spectral Analysis	Yes, by Fourier-transform	Yes, by Fourier-transform	Same as the predicate.
Artifact Evaluation	By manual identification of noise in waveforms and with reference to motion sensor. Additionally provides automated noise detection for convenience.	By manual identification of noise in waveforms and with reference to motion sensor. Additionally provides automated noise detection for convenience.	Same as the predicate.
Dominant Frequency and Amplitude of Myoelectrical Activity	Yes, data tables, and visualization by spectral graphs and myoelectrical waveforms. Amplitude presented as 'BMI-Adjusted Amplitude'.	Yes, data tables, and visualization by spectral graphs and myoelectrical waveforms.	Similar. The subject device presents 'BMI-Adjusted Amplitude' instead of 'Amplitude'. See discussion above on updating the Amplitude plot.

	Gastric Alimetry System	Gastric Alimetry System (predicate)	Discussion
			This update does not impact the performance or safety of the device.
Other Myoelectrical Parameters	Measures of % time in frequency ranges, changes in signal power over time, and cross-channel coupling (wave propagation across the stomach) are available by visual inspection of spectral maps and waveforms. Additionally processes these outputs as tables for convenience. Spectral analysis table includes normative ranges.	Measures of % time in frequency ranges, changes in signal power over time, and cross-channel coupling (wave propagation across the stomach) are available by visual inspection of spectral maps and waveforms. Additionally processes these outputs as tables for convenience.	The subject device includes normative ranges for the spectral analysis parameters. See discussion above on updating the spectral analysis. This update does not impact the performance or safety of the device.
Symptom Outputs	Each symptom severity and symptom event is shown as a function of time. The total symptom burden score is displayed in a table. The average symptom severity for each symptom is shown in a radar plot. The total symptom burden score and symptom event counts are shown using summary bar graphs. The gastric amplitude and symptom severities are shown on a shared axis, normalized so that they can be visually compared. The corresponding correlation coefficients are displayed as a bar graph. Ten questions are presented to the patient on the App during the test. The Patient's response is captured and provided to the clinician in the Gastric Alimetry Report. The responses are grouped under 'depressive symptoms', 'stress symptoms', and 'anxiety	Each symptom severity and symptom event is shown as a function of time. The total symptom burden score is displayed in a table. The average symptom severity for each symptom is shown in a radar plot. The total symptom burden score and symptom event counts are shown using summary bar graphs. The gastric amplitude and symptom severities are shown on a shared axis, normalized so that they can be visually compared. The corresponding correlation coefficients are displayed as a bar graph. Ten questions are presented to the patient on the App during the test. The Patient's response is captured and provided to the clinician in the Gastric Alimetry Report.	The Subject Device groups the mental wellbeing responses under 3 groups. Refer discussion above on updating the Gut-Brain Wellbeing survey responses. This update does not impact the performance or safety of the device.

	Gastric Alimetry System	Gastric Alimetry System (predicate)	Discussion
	symptoms'. Gut-Brain Wellbeing Total Score included.		
Technical / recording quality outputs	Yes. Impedance, motion. Additionally shows Array position and spatial distribution of amplitude for user convenience.	Yes. Impedance, motion. Additionally shows Array position and spatial distribution of amplitude for user convenience.	Same as the predicate.
Safety Features			
Biocompatibility	Array and Reader in contact with the patient.	Array and Reader in contact with the patient.	Same as the predicate.
Software	Setup (including clinical data), device control, data acquisition software and system checks via App running on a tablet.	Setup (including clinical data), device control, data acquisition software and system checks via App running on a tablet.	Same as the predicate.
System Checks	Impedance monitor and connectivity check displayed prior to recordings.	Impedance monitor and connectivity check displayed prior to recordings.	Same as the predicate.
Skin Preparation	Yes. Shave, measure, skin prep with abrasive conductive gel Additional array template marking step for convenience.	Yes. Shave, measure, skin prep with abrasive conductive gel Additional array template marking step for convenience.	Same as the predicate.
Instructions to Patient	Yes. User instructs patient to limit movement, talking and sleeping. Additional step of displaying these instructions to patient via App as an added safety measure.	Yes. User instructs patient to limit movement, talking and sleeping. Additional step of displaying these instructions to patient via App as an added safety measure.	Same as the predicate.
Sterilization	Electrodes are disposable, non-sterile. Reader and Dock are reprocessed, not supplied sterile. Cleaning and disinfection instructions using wipes provided.	Electrodes are disposable, non-sterile. Reader and Dock are reprocessed, not supplied sterile. Cleaning and disinfection instructions using wipes provided.	Same as the predicate.
Standards with which the Device Complies			Same as the predicate.

	Gastric Alimetry System	Gastric Alimetry System (predicate)	Discussion
Electrodes	ANSI/AAMI EC12:2000 – compliance with relevant requirements.	ANSI/AAMI EC12:2000 – compliance with relevant requirements.	Same as the predicate.
Medical Electrical Equipment	IEC 60601-1	IEC 60601-1	Same as the predicate.
Electromagnetic Compatibility	IEC 60601-1-2	IEC 60601-1-2	Same as the predicate.

Performance Data

The modifications to the device since the prior clearances, namely additional Symptom Summary panel, Symptom Correlation Analysis panel, additional Gut-Brain Wellbeing questions, and an update to the Reader's enclosure, were minimal and did not significantly impact the safety or performance of the device as reflected in the previously performed bench testing, the testing submitted in the prior 510(k) notice remains applicable.

Conclusions

The modified Gastric Alimetry System is as safe and effective as the Gastric Alimetry System. The Gastric Alimetry System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the modified Gastric Alimetry System and its predicate device raise no new issues of safety or effectiveness.