December 5, 2025

Alimetry Ltd.
% Lina Kontos
Regulatory Counsel
Hogan Lovells US LLP
555 Thirteenth Street NW
Washington, District of Columbia 20004

Re: K252504
Trade/Device Name: Gastric Alimetry
Regulation Number: 21 CFR 876.1735
Regulation Name: Electrogastrography System
Regulatory Class: Class II
Product Code: MYE
Dated: August 8, 2025
Received: August 8, 2025

Dear Lina Kontos:

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,

SIVAKAMI VENKATACHALAM -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252504 ?

Please provide the device trade name(s). ?

Gastric Alimetry

Please provide your Indications for Use below. ?

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

Please select the types of uses (select one or both, as applicable). ?

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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: 8 August 2025

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 (K240946) (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:

Modifications to the Gastric Alimetry Algorithm:
- Replacement of the existing signal noise filter with a convolutional neural network (CNN) and additional updates to the processing pipeline of the algorithm to improve performance.

Modifications to the Gastric Alimetry Report:
- Addition of grouping symptoms into subgroups, including an overall symptom score per subgroup.
- Updating presentation of spectral and symptom data.
- Addition of symptom tags to describe common symptom patterns.
- Addition of visual indicators for spectral metrics which are outside of the reference intervals and a summary of the spectral metric values.
- Addition of subgroup scores in the 'Gut-Brain Wellbeing' page.
- Addition of caution statements that are shown on the report when test quality metrics are outside of target ranges and/or non-standard test protocols are used.
- Addition of a plot of average impedance over time and modification of movement index plot.
- Addition of Gut-Brain Wellbeing questions for adolescents between the ages of 12-17 years.
- Removal of guidelines from the report and the release of a separate guidelines document.
- Rearranging information in the reports.

Additional minor updates were made to the Reader, Cloud, Algorithm, App and labeling.

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.

There are no changes to the intended use in the modified Gastric Alimetry System, which has the same intended use as the predicate Gastric Alimetry System (K240946).

Technological Characteristics / Substantial Equivalence

The modified Gastric Alimetry System retains the same core technological characteristics as the predicate Gastric Alimetry system. Both systems utilize identical hardware components: the Alimetry Reader, Gastric Alimetry Array, Gastric Alimetry Dock, and a commercial off-the-shelf iPad mini managed by a mobile device management system. Both systems also utilize an equivalent secure Alimetry Cloud for data storage and access. The fundamental function of recording, storing, viewing, and processing gastric myoelectrical activity remains unchanged, and the general content of the generated reports is similar, with minor modifications:

- Changes to the signal processing pipeline: Replacement of the existing signal noise filter with a convolutional neural network (CNN), increasing the threshold for determining where artifacts were corrected or removed and additional updates to the processing pipeline of the algorithm to improve performance.
- Modifications to the Gastric Alimetry Report, including: Addition of grouping symptoms into nausea & vomiting, pain, postprandial distress, and burning & reflux subgroups, including an overall symptom score per subgroup, removing radar plot, event count, total symptom burden bars, and app use plot from the 'Symptom' pages, addition of symptom tags to describe common symptom patterns and Sensorimotor tags if correlation > 0.5, addition of visual indicators for spectral metrics which are outside of the reference intervals, addition of subgroup scores in the 'Gut-Brain Wellbeing' page and Gut-Brain Wellbeing questions for adolescents, addition of caution statements when test quality metrics are outside of target ranges and/or non-standard test protocols are used, and addition of a plot of average impedance over time.

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 12 years and older	Same as the predicate.
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 12 years and older Specialist GI physicians	Same as the predicate.
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.
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. Both the top ranked and all channels are shown in the supplementary report. Top ranked channels have been moved from the Standard Report to the Supplementary Report.	Yes, all channels.	Same as the predicate. The distribution of information between the Standard and Supplementary Reports has changed, but the same information is still present.
Automated Spectral Analysis	Yes, by short-time Fourier-transform with four-minute windows and 75% overlap, averaged across the top ranked channels. Channels are ranked using a weighted combination of the power, power distribution, impedance, amount of data removed, and in addition, amount of change resulting from smoothing.	Yes, by short-time Fourier-transform with four-minute windows and 75% overlap, averaged across the top ranked channels. Channels are ranked using a weighted combination of the power, power distribution, impedance, and amount of data removed.	Similar. The method for calculating the spectrogram is unchanged. Updates to the parameters used for channel ranking impact a very small proportion of tests. The effect of these updates on test outputs are assessed and shown to be substantially equivalent to the predicate. Therefore, these changes raise no new questions of safety or efficacy.

Artifact Evaluation	By manual identification of noise in waveforms and with reference to motion sensor. Additionally provides automated noise detection for convenience. Detection threshold is slightly less sensitive than predicate threshold. Artifacts in myoelectrical signals are automatically corrected or removed using locked convolutional neural networks (CNNs). Samples with impedance > 1000 kΩ are removed.	By manual identification of noise in waveforms and with reference to motion sensor. Additionally provides automated noise detection for convenience. Artifacts in myoelectrical signals are automatically corrected or removed using a modified Wiener Filter. Samples with impedance > 500 kΩ are removed.	Similar. Artifact detection is substantially equivalent to predicate threshold. The current noise filter is being replaced with convolutional neural networks (CNNs). This difference does not raise any questions of safety or efficacy, as the output of the device is the same with the only difference being the manner in which the signal is processed prior to analysis.
Frequency and Amplitude of Myoelectrical Activity	Yes, data tables, and visualization by spectral graphs and myoelectrical waveforms. Data tables include normative reference intervals. Amplitude presented as 'BMI-Adjusted Amplitude'. Frequency presented as 'Principal Gastric Frequency'. Frequency is not shown in the data tables if the rhythm index is low for a given time period. Frequency and amplitude are not shown if 25% of the data is missing from a given time period.	Yes, data tables, and visualization by spectral graphs and myoelectrical waveforms. Data tables include normative reference intervals. Amplitude presented as 'BMI-Adjusted Amplitude'. Frequency presented as 'Principal Gastric Frequency'. Frequency is not shown in the data tables if amplitude or rhythm index is low for a given time period. Frequency and amplitude are not shown if 50% of the data is missing from a given time period.	Similar. Slight adjustments to the spectral graph, Principal Gastric Frequency calculation, and metric display criteria impact a very small proportion of tests. Spectral graph change does not impact underlying data, only its visual representation. Principal Gastric Frequency is shown to be substantially equivalent to predicate. Therefore, these changes raise no new questions of safety or efficacy.
Other Myoelectrical Parameters	Presented in data tables, and visualization by spectral graphs and myoelectrical waveforms. Measure of rhythmic stability presented as	Presented in data tables, and visualization by spectral graphs and myoelectrical waveforms. Measure of rhythmic stability presented as	Similar. Changes to the rhythm index calculation and metric display criteria impact a very small proportion of tests. The rhythm index

	'Gastric Alimetry Rhythm Index'. Measure of gastric response to meal stimulus presented as 'Fed:Fasted Amplitude Ratio'. Rhythm index and amplitude ratio are not shown if 25% of the data is missing from a given time period. Data tables include normative reference intervals. Other measures of myoelectrical activity (e.g. % time in frequency ranges, wave propagation, etc) can be assessed visually using the spectrogram, amplitude plot, and/or signal traces.	'Gastric Alimetry Rhythm Index'. Measure of gastric response to meal stimulus presented as 'Fed:Fasted Amplitude Ratio'. Rhythm index and amplitude ratio are not shown if 50% of the data is missing from a given time period. Data tables include normative reference intervals. Other measures of myoelectrical activity (e.g. % time in frequency ranges, wave propagation, etc) can be assessed visually using the spectrogram, amplitude plot, and/or signal traces.	and amplitude ratio shown to be substantially equivalent to predicate. Therefore, these changes raise no new questions of safety or efficacy.
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 in the Supplementary Report. In addition, the symptoms are grouped into 'nausea & vomiting', 'pain', 'postprandial distress', and 'burning & reflux' subgroups, including an overall symptom score per subgroup. The symptom event counts are shown under the appropriate symptom subgroups. Patterns of symptoms (Meal Induced, Meal Alleviated, Late Onset, Continuous, or none) are automatically identified beside symptom plots. The gastric amplitude and symptom severities are shown on a shared axis, normalized so that they can	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 (ages 18 and up) on the App during the test. The Patient's response is captured and provided to	Similar. The symptom output presentation has been updated so that the radar plot is replaced by presentation of symptom subgroups and scores. The subject device includes wellbeing questions for patients aged 12 years and older, whereas the predicate limited the survey to patients aged 18 and older. Scores displayed beside the subgroups can be manually verified by summing the individual question responses. The scores do not introduce any new information which

	be visually compared. The corresponding correlation coefficients are displayed as a bar graph. A symptom can be tagged as 'Sensorimotor' if there is a strong correlation with gastric amplitude. Ten questions are presented to the patient (ages 12 and up) 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 symptoms'. A score is displayed beside each subgroup. Gut-Brain Wellbeing Total Score included.	the clinician in the Gastric Alimetry Report. The responses are grouped under 'depressive symptoms', 'stress symptoms', and 'anxiety symptoms'. Gut-Brain Wellbeing Total Score included.	could not already be manually extracted from the survey results.
Technical / recording quality outputs	Yes. Impedance, artifacts, test protocol (test duration, meal type, and meal consumption), BMI. movement. Array position and spatial distribution of amplitude included in the Supplementary Report. Test quality cautions are also included if quality parameters are outside the recommended range.	Yes. Impedance, artifacts, test duration, meal type, meal consumption, BMI, movement. Additionally shows Array position and spatial distribution of amplitude for user convenience.	Similar. The same quality parameters are reported, however the presentation in the subject device is updated and includes cautions when test quality parameters are outside the recommended range. Addition of average impedance time-series plot offers another way to view the existing impedance data (temporally in addition to spatially) and does not impact any other processing. Its intended use is very similar to the

			movement index plot already shown in the Report, so this change raises no new questions of safety or efficacy.
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			

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 updates to the processing pipeline of the algorithm, and modifications to the Report, including addition of grouping symptoms into subgroups with an overall symptom score per subgroup, addition of visual indicators for spectral metrics and caution statements for quality metrics, addition of symptom tags, addition of subgroup scores to wellbeing responses and additional modifications to presentation of data, did not significantly impact the safety or performance of the device as reflected in the performed bench testing, in addition to bench testing submitted in prior 510(k) notices.

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 indications, and similar technological characteristics and principles of operation as its predicate device. The minor technological differences between the modified Gastric Alimetry System and its predicate device raise no new or different questions of safety or effectiveness.