November 17, 2023

Alimetry Ltd.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19115

Re: K232925
Trade/Device Name: Gastric Alimetry System
Regulation Number: 21 CFR 876.1735
Regulation Name: Electrogastrography System
Regulatory Class: Class II
Product Code: MYE
Dated: September 19, 2023
Received: September 19, 2023

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: 06/30/2023
See PRA Statement on last page

510(k) Number *(if known)*
K232925

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.

Type of Use *(Select one or both, as applicable)*

X 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
Alimetry's Gastric Alimetry

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Alimetry Ltd.

Phone: +64 27 622 2306

Contact Person: Yaara Yarmut, Chief Regulatory Officer.
Date Prepared: September 19, 2023

Name of Device and Name/Address of Sponsor

Trade name: Gastric Alimetry

Manufacturer: Alimetry

Address: 70 Symonds St.
Grafton
Auckland 1010
New Zealand

Common name: Gastric Alimetry System

Classification Name:

Electrogastrography system, 21 CFR 876.1735, Product code: MYE

Class II

Predicate and Reference Devices

1. Trade Name: Gastric Alimetry (K223398) (primary predicate)
   Manufacturer: Alimetry Ltd.

Intended Use / Indications for Use

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

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 an array with recording electrodes on an adhesive patch, which is used for recording the myoelectrical data from the skin surface. An App is used to set up the device and capture patient-reported symptom data. A report is provided to the clinicians at the end of the test which 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.

In the modified Gastric Alimetry System, the following updates are introduced:

- Modifications to the patient report to include additional information, as follows:
    - Inclusion of **Symptom Summary** panel in the Gastric Alimetry Report to provide a visual summary of the overall symptom severities currently displayed by the **Symptom Graph**.
    - Inclusion of **Symptom Correlation Analysis** panel in the Gastric Alimetry Report to provide a visual summary of the correlation between symptom severity and gastric amplitude.
    - Inclusion of **Gut-Brain Wellbeing** questions panel in the Gastric Alimetry Report to display the results of ten optional wellbeing questions presented to the patient via the Gastric Alimetry App.
- Update to the design of the **Reader's Enclosure**
- The labeling has been updated to include normative range data to provide reference information for the clinician.

In addition, the following minor updates were introduced:

- Minor firmware changes for efficiency
- Gastric Alimetry App:
    - Cybersecurity updates
    - Update to the user interface of the App to include additional symptom logging
- Alimetry Cloud:
    - Updated to health professional dashboard available to include the session number
    - Addition of multi-factor authentication for user login.
    - Minor Algorithm fixes

Technological Characteristics / Substantial Equivalence

The Gastric Alimetry device has the same intended use and indications for use and technological characteristics as the primary predicate. Both devices are intended to record, store, view and process gastric myoelectrical activity as an aid in the diagnosis of various gastric disorders.

Item	Subject Device	Primary Predicate Device	Discussion
Device	Gastric Alimetry System	Gastric Alimetry System	
Manufacturer / K#	Alimetry Ltd.	Alimetry Ltd. / K223398	

Item	Subject Device	Primary Predicate Device	Discussion
Intended Use and indication for 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.
User Population	Medical professionals to set up and use the system Patients 18 years and older Specialist GI physicians	Medical professionals to set up and use the system Patients 18 years and older Specialist GI physicians	Same as the predicate.
Accessories			
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.
Technological Characteristics			
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.
Data Storage	On data acquisition device and cloud server	On data acquisition device and cloud server	Same as the predicate.
Weight of device on patient	225 grams - Reader and Array	225 grams - Reader and Array	Same as the predicate.

Item	Subject Device	Primary Predicate Device	Discussion
Power Source	Battery powered	Battery powered	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.
Patient Symptom Logging	Available on App interface. Presented as plot with times.	Available on App interface. Presented as plot with times.	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.
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.
Safety Features			
System Checks	Impedance monitor and connectivity check displayed prior to recordings.	Impedance monitor and connectivity check displayed prior to recordings.	Same as the predicate.
Instructions to Patient	Yes. User instructs patient to limit movement, talking and sleeping. These instructions are displayed to the patient via an App as an added safety measure.	Yes. User instructs patient to limit movement, talking and sleeping. These instructions are displayed to the patient via an App as an added safety measure.	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.	By manual identification of noise in waveforms and with reference to motion sensor.	Same as the predicate.

Item	Subject Device	Primary Predicate Device	Discussion
	Additionally provides automated noise detection for convenience.	Additionally provides automated noise detection for convenience.	
Frequency, Amplitude, and Rhythm Stability of Myoelectrical Activity	Yes, data tables, and visualization by spectral graphs and myoelectrical waveforms.	Yes, data tables, and visualization by spectral graphs and myoelectrical waveforms.	Same as the predicate.
Other Myoelectrical Parameters	Measures of % time in frequency ranges and changes in signal power over time are available by visual inspection of spectral maps and waveforms.	Measures of % time in frequency ranges and changes in signal power over time are available by visual inspection of spectral maps and waveforms.	Same as the predicate.
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. Questions are presented to the patient on the App. Patient responses are captured and provided to the clinician in the Gastric Alimetry Report.	Each symptom severity and symptom event is shown as a function of time. The total symptom burden score is displayed in a table. Gut-brain wellbeing questions asked by clinician during patient consultation.	The Subject Device contains additional visualizations of data presented by the Predicate Device without removing or altering any of the existing outputs. Refer discussion above on symptom visualization and correlation analysis. The addition of the gut-brain wellbeing questions into the app and report does not impact the performance of the device.
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.

Standards with which the Device Complies			
Electrodes	ANSI/AAMI EC12 –compliance with relevant requirements.	ANSI/AAMI EC12 –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. For completeness, the company repeated the array electrical performance testing on the final version of the device with the thinner gel that was incorporated into the device design addressed in K213924.

No clinical studies were required.

Substantial Equivalence

The modified Gastric Alimetry System has the same intended uses and the same indications, technological characteristics, and principles of operation as its predicate device, the Gastric Alimetry System. The minor technological differences between the Gastric Alimetry and its predicate device do not raise different questions of safety or effectiveness. Therefore the modified Gastric Alimetry System is shown to be substantially equivalent.