June 3, 2022

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

Re: K213924
Trade/Device Name: Gastric Alimetry System
Regulation Number: 21 CFR 876.1735
Regulation Name: Electrogastrography system
Regulatory Class: Class II
Product Code: MYE
Dated: December 15, 2021
Received: December 15, 2021

Dear Ms. 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 (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, 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)*
K213924

Device Name
Gastric Alimetry System

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)*

☒ 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 27 609 1886
Facsimile: -
Contact Person: Yaara Yarmut, Chief Regulatory Officer.
Date Prepared: December 15, 2021

## 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 Devices

Trade Name: Polygraf ID with POLYGRAM NET ElectroGastroGraphy Application Software (K014269)
Manufacturer: Medtronic A/S

## 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 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 the myoelectrical data and movement artifacts through an array with recording electrodes on an adhesive patch which is used for recording the myoelectrical data from the skin surface. An App 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 displays myoelectrical data.

**Technological Characteristics / Substantial Equivalence**

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

| | **Gastric Alimetry** | **Medtronic Polygram NET Electrogastrography (EGG) System (K014269)** |
|---|---|---|
| **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, process and view gastric myoelectrical activity as an aid to the diagnosis of gastrointestinal motility disorders |
| **Electrodes** | Disposable; Peel-and-stick patch. | Disposable; Placed individually. |
| **Sampling Frequency** | 4 Hz | 1Hz |
| **Low Frequency Range** | DC | DC |
| **High frequency range** | 2 Hz | 0.5 Hz |
| **Number of channels** | 8 displayed<br>64 (+2 reference) | 4 (+2 reference) |
| **Electrode to recorder interface** | Reader located on the Array and directly connected to it. | Electrodes connected to recorder with cables. |
| **Screen** | Dedicated tablet for system operation | Connected to a desktop computer for system operation |
| **Motion Sensor** | Accelerometer | Accelerometer |
| **Power Source** | Battery powered | Connected to the mains power supply |
| **Patient Symptom Logging** | Available on App interface. | Available on desktop interface. |

**Performance Data**

Testing was performed to verify device specifications and confirm the safety and performance of the device. In all instances, the Gastric Alimetry functioned as intended. Testing comprised:

- Biocompatibility testing addressing cytotoxicity, sensitization, and skin irritation in accordance with ISO 10993

- Cleaning and disinfection validation of reusable components
- Package validation
- Shelf life validation
- Software verification and validation
- Electromagnetic compatibility in accordance with IEC 60601-1-2:2014 4th edition and FCC 47 CFR Part 15 subpart C 2021.
- Electrical safety in accordance with IEC 60601-1:2005 + A1:2012
- Human factors evaluation by medical professional to address placement of the array and comprehension of the report

A prospective clinical study was undertaken on a total of 25 patients aged 18 and over with various gastric disorders. This was a simultaneous head-to-head comparison to the predicate to evaluate the mean of the frequency of the raw data recorded from the predicate electrode channels vs identically positioned channels recorded simultaneously with the Gastric Alimetry System. The results demonstrate that the Gastric Alimetry System detects and measures gastric myoelectrical frequency across pre-prandial and postprandial periods in an equivalent manner to the predicate device within a cohort of patients with various gastric disorders who form the target population for the device in clinical practice. Minimal adverse events were observed, with all reported events being minor and transient and predominantly related to irritation at the site of the electrodes.

Additional clinical study data was used to evaluate the sensitivity and specificity of the artifact detection algorithm against manual marking of artifacts by clinicians. These data demonstrated that the automated artifact detection algorithm is comparable to manual marking.

**Substantial Equivalence**

The Gastric Alimetry has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Gastric Alimetry and its predicate devices do not raise different questions of safety or effectiveness. Performance data demonstrate that the Gastric Alimetry is as safe and effective as the Polygraf ID with Electrogastrography System. Thus, the Gastric Alimetry is substantially equivalent to the predicate.