September 9, 2025

CardioSet Medical Ltd.
℅ John Smith
Partner
Hogan Lovells LLP
555 13th St. NW
Washington, District of Columbia 20004

Re: K250922
Trade/Device Name: Edema Guard Monitor (EGM) CardioSet-001
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II
Product Code: DSB
Dated: August 7, 2025
Received: August 7, 2025

Dear John Smith:

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,

Stephen C. Browning -S

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular 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)*
K250922

Device Name
Edema Guard Monitor (EGM) CardioSet-001

Indications for Use *(Describe)*
The EGM CardioSet-001 is intended for patients with any of the following conditions:
- With fluid management problems
- Taking diuretic medication
- Living with heart failure
- Suffering or recovering from a coronary artery disease-related event

This device is intended for use under the direction of a physician, for the non-invasive monitoring and management of patients with fluid management problems in both the inpatient and outpatient setting.

The EGM CardioSet-001 reading is intended to be used as an adjunct parameter to standard clinical assessment methods and should not be the sole input used to guide treatment.

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.

K250922

510(K) SUMMARY

CardioSet Medical Ltd.'s Edema Guard Monitor (EGM) (CardioSet-001)

Submitter:

Submitter Business: CardioSet Medical Ltd.

Submitter Address: Havazelet 26. Matan, Israel 4585800

Submitter Contact: Mr. Assaf Gur

Submitter Phone Number: +972546603111

Submitter Email: assafgur@gmail.com

Correspondent:

Correspondent Business: Hogan Lovells US LLP

Correspondent Address: 555 13th St. NW Washington, DC 20004 United States

Correspondent Contact: Dr. John Smith

Correspondent Phone Number: (202) 637-3638

Correspondent Fax Number: (202) 637-5910

Correspondent Email: john.smith@hoganlovells.com

Date Prepared: July 30, 2025

Name of Device: Edema Guard Monitor (EGM) (CardioSet-001)

Common or Usual Name: Impedance plethysmograph

Classification Name: Plethysmograph, Impedance

Regulation Number: 21 CFR 870.2770

Product Code: DSB

Predicate:

Predicate Trade Name: Zoe Fluid Status Monitor

Predicate #: K133301

Product Code: DSB

Predicate Contact: Noninvasive Medical Technologies, Inc.
6412 S. Arville St. Las Vegas, NV 922614
Predicate Contact Phone: (888) 906-0413
Predicate Contact Fax: (702) 614-4170

Device Description:

The Edema Guard Monitor (EGM) CardioSer-001 is a non-invasive, battery powered impedance monitor designed as an 'early warning' monitor for determining changes in the fluid status of patients with fluid management problems. The EGM CardioSet-001 works by applying a low amplitude, high frequency electrical current to the body and measuring the electrical impedance. By separately monitoring the impedance of various electrode pairs, the impedance due to the thoracic cavity can be isolated, improving device sensitivity. Base Impedance decreases when fluid increases and increases when fluid decreases.

The EGM CardioSet-001 is designed for use with commercially available electrodes which are positioned with the assistance of the supplied templates.

Intended Use / Indications for Use:

The EGM CardioSet-001 is intended for patients with any of the following conditions:

- With fluid management problems
- Taking diuretic medication
- Living with heart failure
- Suffering or recovering from a coronary artery disease-related event

This device is intended for use under the direction of a physician, for the non-invasive monitoring and management of patients with fluid management problems in both the inpatient and outpatient setting.

The EGM CardioSet-001 reading is intended to be used as an adjunct parameter to standard clinical assessment methods and should not be the sole input used to guide treatment.

Indications for Use Comparison:

The Indications for Use of the subject device are a subset of those cleared for the predicate device, meeting the first requirement for finding substantial equivalence.

Technological Comparison:

Both the subject and predicate device use the same technology of measuring lung bioimpedance in order to monitor pulmonary congestion. Both systems do this by applying electrodes on the skin. Other system components are also similar. Both systems are controlled via local software only (no external/cloud communication) and display their output to the physician on a console (predicate) or on

the device's display. The subject device is powered via a battery; the predicate device can also be used with battery power. The current transmitted to the electrodes has identical frequency (100 kHz) and its amplitude is of the same order of magnitude.

While the predicate device is designed for use with disposable, self-adhesive silver/silver chloride electrodes available from a specific provider, the subject device is designed for use with any standard ECG electrode and includes a self-check to ensure each electrode has a reasonable impedance. The predicate uses only 2 electrodes – one above the breastbone and one below the breastbone – while the subject device has six electrodes that are attached to the chest in specified locations (3 sensors on the front and 3 on the back) with the assistance of the templates provided with the device. The technological differences in location and number of electrodes do not raise different questions and are expected to provide at least equivalent lung fluid content calculation as demonstrated by bench, animal, and clinical study. The differences in the number and location of electrodes is in order to overcome the two largest challenges with obtaining sensitive measurement of lung congestion using bioimpedance.

Non-Clinical and/or Clinical Tests Summary & Conclusions:

Bench testing was performed to demonstrate the accuracy of impedance measurements and support general electrode compatibility.

Animal testing was performed to correlate impedance measurements with amount of lung congestion.

Side by side comparison of impedance measurements of both the subject and clinically studied device versions was performed to demonstrate equivalent performance.

The company has performed several clinical trials using the previous version of the EGM (RSMM 207) which were published between 2001 - 2012. The primary goal of the first clinical study (Charach et al., 2001) was to demonstrate proof of concept that the significantly different LIs were measured for patient that did and did not develop AHF. The second study (Shochat et al., 2006) determines the threshold where a relative change in LI from initial is clinically significant and provides a strong prediction of imminent presentation of AHF. The third study (Shochat et al., 2012) demonstrated that using this threshold to inform clinical treatment resulted in better clinical outcomes, both in the short and long term.

The provided performance testing demonstrated that the subject device can accurately measure lung impedance as described in the intended use above and is thus substantially equivalent to the referenced predicate device.