February 20, 2025

CardioCalm Srl
Fabio Badilini
President
Corso Martiri della Libertà, nr. 40
Montichiari, BS 25018
Italy

Re: K243312
Trade/Device Name: CER-S
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: January 22, 2025
Received: January 22, 2025

Dear Fabio Badilini:

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,

Jennifer W. Shih -S

Jennifer Kozen
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243312

Device Name

CER-S

Indications for Use *(Describe)*

CER-S is a medical device stand-alone software intended for the analysis, editing, review and reporting of continuous ECG digital recordings, to support the clinician in the interpretation of the trace and the diagnosis of cardiac rhythm disorders in adult and pediatric patients.
CER-S is intended for use in clinical and hospital settings only by qualified medical personnel or adequately trained professional personnel working under the supervision and responsibility of a clinician. Users must undergo a thorough software training before using the medical device.
This device does not provide an automated interpretation and is not intended for use as the only diagnostic tool.
CER-S analysis provides indications for evaluation of:
• Patients with rhythm disturbances (cardiac arrhythmias),
• Patients with transient myocardial ischemia,
• Patients with pacemaker (only if pacing detection is available from the input recording),
• Patients needing HRV evaluation,
• Newborn patients limited to QRS detection.

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.

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"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
(as required by 21 CFR 807.92)

Submitter	CardioCalm Srl
	Corso Martiri della Libertà, nr. 40 25018 Montichiari (BS)
Telephone	+ 39 030 9650745
Fax	+ 39 030 9650572

Contact Person	Fabio Badilini President & Legal Representative
Address	Corso Martiri della Libertà, nr. 40
Telephone	+ 39 030 9650745
Fax	+ 39 030 9650572
Email	badilini@cardiocalm.com

Date Prepared	21/10/2024

Trade Name	CER-S
Common Name	Continuous ECG Recording - Suite
Panel Code	Cardiovascular/74
Classification Name	Computer diagnostic, programmable
Class	Class II
Regulation Number	21 CFR 870.1425
Regulation Description	Programmable diagnostic computer
Product Code	DQK

Name of Predicate Device	**510(k) #**	**Manufacturer**
CER-S	K213861	CardioCalm Srl

Reason for Submission	Intention to introduce into commercial distribution a device, CER-S, that has undergone significant changes that could affect the substantial equivalence with the predicate device.

Device Description	CER-S is a tool, designed to offer a framework for the interaction of different software-modules, providing advanced solutions for Continuous ECG Recording (CER). Different modules provide: • ECG Beat detection and classification, • analysis of ECG rhythm, arrhythmia detection, • interactive Viewer and set of tools to perform editing of ECG beats, Rhythm annotations and noise Windows, • interactive Continuous ECG Viewer, • interactive display/management of ECG Templates, • holter-like report for analyzed Continuous ECG records, • record exportation, in ISHNE format, generation of aECG FDA HL7 XML (v. 2). Note: The automatic analysis is limited to data acquired from electrodes with conductive paste/gel (dry and dry/metal electrodes are not intended to be used) placed on standard location in compatible formats from any device used for the arrhythmia diagnostics such as Holter, event recorder, 12-lead ambulatory ECG devices when assessment of the rhythm is necessary. Moreover, CER-S allows the automatic analysis for the following patch location: • two-electrode patches positioned in the left upper chest area at a roughly inclined angle • three-electrode triangular shape patches positioned on the patient's left upper chest area below the 1st rib, at an inclined angle • three-electrode T-shaped patches positioned in the center-thoracic position between the upper part of the chest (manubrium) and the sternum In all cases, patch placement must strictly follow the indication provided by the manufacturer of the certified-patch device.
Indications for use	CER-S is a medical device stand-alone software intended for the analysis, editing, review and reporting of continuous ECG digital recordings, to support the clinician in the interpretation of the trace and the diagnosis of cardiac rhythm disorders in adult and pediatric patients. CER-S is intended for use in clinical and hospital settings only by qualified medical personnel or adequately trained professional personnel working under the supervision and responsibility of a clinician. Users must undergo a thorough software training before using the medical device.

	This device does not provide an automated interpretation and is not intended for use as the only diagnostic tool. CER-S analysis provides indications for evaluation of: • Patients with rhythm disturbances (cardiac arrhythmias), • Patients with transient myocardial ischemia, • Patients with pacemaker (only if pacing detection is available from the input recording), • Patients needing HRV evaluation, • Newborn patients limited to QRS detection.

Substantial Equivalence	The fundamental scientific principles and technological characteristic, including the indications for use and general design are equivalent to the predicate device, as summarized hereafter: • Software type, Holter Analyzer, PC based SaMD, working in Windows Operative System, as the predicate, • Patient population, adults and pediatrics, as the predicate, • User groups: qualified medical personnel or adequately trained professional personnel working under the supervision and responsibility of a clinician, equivalent to predicate device, • Indications for use, equivalent to the predicate, • Environmental use, equivalent to the predicate. The subject device introduces significant improvements over the predicate device. The main modifications can be summarized as follows: • Enhanced software usability, • Option to activate and run pacemaker analysis, • Overall optimization of embedded algorithms for beat and noise detection, rhythm analysis and beat measurements, • Strengthened cybersecurity measures. In conclusion, the subject device has the same intended use as the predicate device, and any differences in technological characteristics do not raise different questions of safety or effectiveness.

Performance Data	Non-clinical tests have been conducted on the Subject Device: - ECG performance testing, according to: o IEC 60601-2-47:2012 (Recognition Number 3-155) o IEC 60601-2-25:2011 (Recognition Number 3-105) - Software development life cycle, according to: o IEC 62304:2015 (Recognition Number 13-79) - Usability engineering process, according to: o IEC 62366-1:2020 (Recognition Number 5-129) - Any potential hazards have been evaluated and controlled through Risk Management activities, according to: o ISO 14971:2019 (Recognition Number 5-125) The testing demonstrated that CER-S is substantially equivalent to the predicate for the proposed intended use. No clinical tests were performed to demonstrate the substantial equivalence of CER-S.

Conclusion	Based on the indications for use, technological characteristics, and comparison to predicate devices, the Subject device CER-S has been shown to be substantially equivalent to the legally marketed predicate devices.