April 25, 2022

CardioCalm Srl
Fabio Badilini
President
Via Martiri della Liberta, nr. 40
Montichiari, Brescia 25018
Italy

Re: K213861
Trade/Device Name: CER-S
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: March 24, 2022
Received: March 29, 2022

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 (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,

Jennifer Shih 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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K213861

Device Name
CER-S

Indications for Use *(Describe)*
CER-S is a stand-alone software medical device intended to analyze, edit, review and report digital continuous ECG recordings.

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.

The device provides the clinician an additional tool to aid in the interpretation of ECG data for diagnosis of heart rhythm disorders in adult and pediatric patients.

Note: 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.**

# 510(k) Summary
(as required by 21 CFR 807.92)

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| Submitter | CardioCalm Srl |
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| Date Prepared | 17/11/2021 |

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| 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 | K193177 | CardioCalm Srl |

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| **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. |

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| **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).<br>Different modules provide:<br>• ECG Beat detection and classification<br>• Analysis of ECG rhythm, arrhythmia detection<br>• interactive Viewer and set of tools to perform editing of ECG beats, Rhythm annotations and noise Windows<br>• interactive Continuous ECG Viewer<br>• interactive display/management of ECG Templates<br>• Holter-like report for analyzed Continuous ECG records, record exportation, in ISHNE format<br>• generation of aECG FDA HL7 XML (v. 2), for the submission of continuous ECG recording to the FDA ECG Warehouse.<br><br>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:<br>• two-electrode patches positioned in the left upper chest area at a roughly inclined angle<br>• three-electrode triangular shape patches positioned on the patient's left upper chest area below the 1st rib, at an inclined angle<br>• three-electrode T-shaped patches positioned in the center-thoracic position between the upper part of the chest (manubrium) and the sternum<br>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 stand-alone software medical device intended to analyze, edit, review and report digital continuous ECG recordings.<br>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 |

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| | clinician. Users must undergo a thorough software training before using the medical device.<br>The device provides the clinician an additional tool to aid in the interpretation of ECG data for diagnosis of heart rhythm disorders in adult and pediatric patients.<br>Note: This device does not provide an automated interpretation and is not intended for use as the only diagnostic tool.<br>CER-S analysis provides indications for evaluation of:<br>• Patients with rhythm disturbances (cardiac arrhythmias),<br>• Patients with transient myocardial ischemia,<br>• Patients with pacemaker (only if pacing detection is available from the input recording),<br>• Patients needing HRV evaluation,<br>• Newborn patients limited to QRS detection. |

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| **Technological Characteristics and 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:<br>• Software type, Holter Analyzer, working in Windows Operative System, as the predicate;<br>• Patient population, adults and pediatrics;<br>• User groups: qualified medical personnel or adequately trained professional personnel working under the supervision and responsibility of a clinician., equivalent to predicate device;<br>• Indications for use, equivalent to the predicate;<br>• Environmental use, equivalent to the predicate.<br><br>The technological characteristics of the subject device and the predicate device are substantially equivalent to the predicate.<br>As for the predicate device described below, the Subject device is a PC based SaMD, working in Windows Operative System.<br><br>The following significant differences exist between the subject and predicate devices:<br>• The subject device improves the performance in beat detection in recordings with low amplitude and with noise;<br>• The subject device improves the performance of the beat measures in recording with higher heart rate;<br>• The subject device allows HRV measurements in the frequency domain and Sinus Tachycardia detection;<br>Further minor changes in subject device are developed to enhance the usability of the software and the graphic interface of some its components, which provides a smooth and faster editing of automatically detected arrhythmic events. |

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| **Performance Data** | Non-clinical tests have been conducted on the Subject Device:<br>- ECG performance testing, according to:<br>o ANSI/AAMI EC57:1998/(R)2003 and IEC 60601-2-47:2012 (Recognition Number 3-155)<br>o IEC 60601-2-25:2011 (Recognition Number 3-105)<br><br>- Software development life cycle, according to:<br>o IEC 62304:2006+A1:2015 (Recognition Number 13-79)<br><br>- Usability engineering process, according to:<br>o IEC 62366-1:2015+AMD1:2020 (Recognition Number 5-129)<br><br>- Any potential hazards have been evaluated and controlled through Risk Management activities, according to:<br>o ISO 14971:2019 (Recognition Number 5-125)<br><br>The testing demonstrated that CER-S is substantially equivalent to the predicate for the proposed intended use.<br>No clinical tests were performed to demonstrate the substantial equivalence of CER-S. |

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| **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. |