



August 26, 2020

CardioCalm
Fabio Badilini
President & Legal Representative
Corso Martiri della Libertà, nr. 40
Montichiari, 25018, Italy

Re: K193177
Trade/Device Name: CER-S
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: July 17, 2020
Received: July 27, 2020

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,

for

Jennifer Shih
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K193177

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, but not limited to, 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.

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Traditional 510(k) Premarket Notification
CER-S

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

Submitter	CardioCalm
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Date Prepared	10/29/2019
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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
SyneScopeTM, EasyScopeTM, SyneComTM HolterReader	K042002	Sorin Group (Ela Medical, Inc)

Reason for Submission	Pre-market notification for CER-S, a new Device, seeking authority to market the product under Section 510(k), as substantially equivalent to the Predicate Devices listed above, legally marketed on US territory.
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Device Description	<p>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).</p> <p>Different modules provide:</p> <ul style="list-style-type: none"> • 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), for the submission of continuous ECG recording to the FDA ECG Warehouse. <p>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:</p> <ul style="list-style-type: none"> • 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 <p>In all cases, patch placement must strictly follow the indication provided by the manufacturer of the certified-patch device.</p>
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Traditional 510(k) Premarket Notification CER-S

Indications for use	<p>CER-S is a stand-alone software medical device intended to analyze, edit, review and report digital continuous ECG recordings.</p> <p>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.</p> <p>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.</p> <p>Note: This device does not provide an automated interpretation and is not intended for use as the only diagnostic tool.</p> <p>CER-S analysis provides indications for, but not limited to, evaluation of:</p> <ul style="list-style-type: none"> • 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.
Technological Characteristics and Substantial Equivalence	<p>The fundamental scientific principles and technological characteristic, including the indications for use and general design are equivalent to the predicate device, as summarized hereafter:</p> <ul style="list-style-type: none"> • Software type, Holter Analyzer, working in Windows Operative System, as the predicate; • Patient population, adults and pediatrics; • User groups: trained operators under the direct supervision of a licensed healthcare practitioner, equivalent to predicate device; • Indications for use, equivalent to the predicate; • Environmental use, equivalent to the predicate. <p>The technological characteristics of the subject device and the predicate device are substantially equivalent to the predicate.</p> <p>As for the predicate device described below, the Subject device is a PC based SaMD, working in Windows Operative System</p>
Performance Data	<p>The following non-clinical tests have been conducted on the Subject Device:</p> <ul style="list-style-type: none"> - ECG performance testing, according to: <ul style="list-style-type: none"> o ANSI/AAMI EC57:1998/(R)2003 and 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: <ul style="list-style-type: none"> o ANSI AAMI IEC 62304:2006 (Recognition Number 13-32) - Usability engineering process, according to: <ul style="list-style-type: none"> o IEC 62366:2007 <p>Any potential hazards have been evaluated and controlled through Risk Management activities. The testing demonstrated that CER-S is safe and effectiveness for the propose intended use. No clinical tests were performed to demonstrate safety and effectiveness of CER-S</p>
Conclusion	<p>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 and is safe and effective for its intended use.</p>