June 6, 2023

Ordinatrum Solutions
℅ H. Semih Oktay, Ph.D.
President
CardioMed Device Consultants, LLC.
3168 Braverton Street Suite 200
Edgewater, MD 21037

Re: K220117
Trade/Device Name: ARC Intensive Care Information System (ARC System)
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, OUG
Dated: May 5, 2023
Received: May 5, 2023

Dear Semih Oktay:

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,

Robert T. Kazmierski -S

for

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)*
K220177

Device Name
ARC System

Indications for Use *(Describe)*

The ARC System is an intensive care information system indicated for aggregating, displaying, and managing physiologic and other patient information. The system collects and displays data from FDA-cleared patient bedside medical devices and patient information systems. The Arc System allows healthcare professionals to define rule-based algorithms to receive notifications for patient prioritization and continuous patient monitoring.

The ARC System software is intended to be used by healthcare professionals for the following purposes:
• To remotely consult, regarding a patient's status
• To remotely review other standard or critical near real-time patient data, waveforms, and alarms in order to utilize this information to aid in clinical decisions and deliver patient care
• To create and manage Patient Prioritization Rules
• To access Patient Prioritization information
WARNING:
• Rx Only.
• Do not use the ARC System as an active patient monitoring.
• Do not use the ARC System to replace any part of the hospital's device monitoring.
• Do not rely on the ARC System software as the sole source of patient status information.

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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1. 510(k) Summary

In accordance with 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Applicant:

Submitter name:	Ordinatrum Solutions
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Official Correspondent:

Contact person:	Semih Oktay, Ph.D.
Phone:	(410)271-2088
E-Mail:	soktay@cardiomedllc.com
Date prepared:	June 6th, 2023

Device Name:

Proprietary name:	ARC Intensive Care Information System (ARC System)
510(k) number:	K220117
Common name:	Physiological Patient Monitor (without arrhythmia detection or alarms)
Classification name:	Class II, 21 CFR§870.2300, Cardiac monitor (including cardiotachometer and rate alarm)
Product code:	MWI

Indications for Use:

The ARC System is an intensive care information system indicated for aggregating, displaying, and managing physiologic and other patient information. The system collects and displays data from FDA-cleared patient bedside medical devices and patient information systems. The Arc System allows healthcare professionals to define rule-based algorithms to receive notifications for patient prioritization and continuous patient monitoring.

The ARC System software is intended to be used by healthcare professionals for the following purposes:

- To remotely consult, regarding a patient's status
- To remotely review other standard or critical near real-time patient data, waveforms, and alarms in order to utilize this information to aid in clinical decisions and deliver patient care
- To create and manage Patient Prioritization Rules
- To access Patient Prioritization information

WARNING:

- Rx Only.
- Do not use the ARC System as an active patient monitoring.
- Do not use the ARC System to replace any part of the hospital's device monitoring.
- Do not rely on the ARC System software as the sole source of patient status information.

Device Description:
The ARC ICU Information System is intended to provide the Intensive Care Unit (ICU) with clinical decision support, workflow management, interoperability and device connectivity. The system receives near real-time data from medical devices in the ICU and presents them on a single dashboard to provide secondary clinical decision support. Patient vitals from ventilators, monitors, pumps, smart beds, IoT sensors etc. are connected to the ARC Box. From the ARC Box, data is propagated through the ARC software, and displayed on a central monitoring system, the ARC DS. The data is available on remote monitoring devices, such as a mobile device or physician tablet. The ARC System is composed of a physical hardware component (ARC Box), which interfaces with the ICU medical devices, and the ARC System Software components.

Decision support algorithms, treatment protocols and applications used within ARC System do not come with a predefined practice, procedure or standard. A skilled health care professional can use ARC System to create and define a healthcare workflow dynamically on the basis of an individual hospital, clinic or physician. ARC ICIS is a Web-based and Cloud Ready system that is built on IoMT and BigData technologies. It is intended to provide reliable and secure access to patient information.

ARC Box is a vendor-neutral connectivity solution that retrieves patient data from different device makers and transfers this data, via serial ports and/or ethernet ports, to a central dashboard. It is built on IoT for secure and quick communication between medical devices while gathering rich data. It temporarily stores data in the event of unexpected circumstances such as power outage or server failure and transfers saved data to ARC ICIS to be visualized for Clinical Decision Support.

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

Predicate Device:
Substantial Equivalence is claimed with the device, K141206 – Decision Health Patient Dashboard manufactured by Decision Health, Inc. on the basis of equivalent intended use / indications for use, technological characteristics and principle of operation.

Comparison of Technological Characteristics:
The table below provides a comparison of the predominant technical characteristics of the new device and the legally marketed predicate device.

Comparison of Technological Characteristics

System Information	ARC ICU Information System	Predicate Device
510(k) Number	K220177	K142106
Device Trade Name	ARC System	Decisio Health Patient Dashboard
Classification Regulation	Class II, 870.2300	Same
Product Code(s)	MWI, Monitor, Physiological, Patient (Without Arrhythmia Detection or Alarms)	Same
Indications for Use	The ARC System is an intensive care information system indicated for aggregating, displaying, and managing physiologic and other patient information. The system collects and displays data from FDA-cleared patient bedside medical devices and patient information systems. The Arc System allows healthcare professionals to define rule-based algorithms to receive notifications for patient prioritization and continuous patient monitoring. The ARC System software is intended to be used by healthcare professionals for the following purposes: ● To remotely consult, regarding a patient's status ● To remotely review other standard or critical near real-time patient data, waveforms, and alarms in order to utilize this information to aid in clinical decisions and deliver patient care ● To create and manage Patient Prioritization Rules ● To access Patient Prioritization information WARNING: ● Rx Only. ● Do not use the ARC System as an active patient monitoring. ● Do not use the ARC System to replace any part of the hospital's device monitoring. ● Do not rely on the ARC System software as the sole source of patient status information.	The Decisio Health Patient Dashboard is a decision support device indicated for aggregating, displaying, and managing physiologic and other patient information. This information is generated by third party medical devices and patient information systems. The device performs automated calculations on patient data collected by third party devices based on approved clinical protocols at patient care facilities. The Decisio Health Patient Dashboard is intended for use by clinicians in healthcare facilities.
Intended Use	The ARC System is intended to provide Intensive Care Unit (ICU) clinical staff decision support, workflow management, interoperability and device connectivity.	Same
Target patient population	Adults	Same

System Information	ARC ICU Information System	Predicate Device
Intended User	Clinicians in healthcare facilities; Administrators; Physicians: Nurses	Same
Display Features	Computer or Mobile device (app)	Patient monitor, computer, or a mobile device
Connectivity	Web-based	Same
Inputs	FDA Cleared Devices: EMR Vital signs monitors Ventilators IV Pumps Foley Catheters	Same
Hardware Specifications	Ports: Serial (rs-232) port, Ethernet (tcp) port, HTTPS ports	Similar
	Protocols: Tcp, Https (443,8080)	
Use Environments	Intensive Care Unit	Same
Alarms	Yes	N/A
Supportive Testing	Software Validation; Cybersecurity; human factors; Unit, integration and system level testing, IEC 60601-1-8	Similar
Software Level of Concern	Moderate	Similar
Sterilization	Non-sterile	Same
Shelf Life	Not likely to be susceptible to degradation	Same
Biocompatibility	No direct nor indirect tissue-contacting components	Same

The ARC ICU Information System has the same intended use and similar technological characteristics as the predicate device. Although there are some differences in indications for use specificity, this level of clarity aligns with other ICIS-type software under product code MWI.

The ARC system is different from the predicate device with regards to the difference in what platform patient data is displayed on. The ARC system does not include display features on the patient monitor. The Arc System allows healthcare professionals to define rule-based algorithms to receive notifications for patient prioritization and continuous patient monitoring, including receiving pass-through alarms. Testing has demonstrated that differences in the technological characteristics will have no impact on safety or effectiveness.

Summary of Testing:
Performance testing to demonstrate substantial equivalence and ensure that the ARC System performs as intended has been conducted. Unit, integration, security, vulnerability and system level testing demonstrated that the ARC System meets its specifications. A human factors usability study has been completed evaluating 30 typical users (15 intensivists and 15 critical care nurses).

Conclusion:
The information included in this submission demonstrates that the ARC System is substantially equivalent to the predicate device (K142106). Although there are minor differences noted between the proposed system and the predicate device, these differences do not raise significant new questions of safety or effectiveness.