Medusa Medical Technologies Inc.
c/o Dr. Diane Sudduth
Senior Consultant QA
Emergo Group, Inc.
816 Congress Ave., Suite 1400
Austin, Texas 78701

September 1, 2023

Re: K131272
Trade/Device Name: Siren ePCR Suite™
Regulation Number: 21 CFR 870.2450
Regulation Name: Medical Cathode-ray Tube Display
Regulatory Class: Class II
Product Code: DXJ

Dear Dr. Diane Sudduth:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated January 3, 2014. Specifically, FDA is updating this SE Letter to remove the secondary product code NSX as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter, please contact Aneesh Deoras, OHT2: Office of Cardiovascular Devices, 240-402-4363, Aneesh.Deoras@fda.hhs.gov.

Sincerely,

Aneesh S. Deoras -S

for

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 3, 2014

Medusa Medical Technologies, Incorporated
C/O Dr. Diane Sudduth
Senior Consultant, QA
Emergo Group, Incorporated
816 Congress Avenue, Suite 1400
Austin, TX 78701

Re: K131272
Trade/Device Name: Medusa Medical Technologies, Inc. Siren ePCR Suite
Regulation Number: 21 CFR 870.2450
Regulation Name: Medical Cathode-Ray Tube Display
Regulatory Class: II
Product Code: DXJ, NSX
Dated: November 18, 2013
Received: November 19, 2013

Dear Dr. Sudduth:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K131272

Device Name: Siren ePCR Suite™

Indications for Use:

Siren ePCR Suite™ is intended for the collection, storage and printing of patient data that is entered by a user (paramedic), or captured from specified medical devices, and integrated into a patient care report (patient electronic medical record). Siren ePCR Suite™ is intended for use by qualified medical personnel providing direct patient care in the pre-hospital environment to document the care provided. Siren ePCR Suite™ is indicated for use by health care providers whenever there is a need for generation of a patient record.

Prescription Use____x_____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by
Richard C. Chapman
Date: 2014.01.02
11:33:26 -05'00'

510(k) Summary

1. Submission Sponsor

Medusa Medical Technologies Inc.
Suite 140-36 Solutions Dr
Halifax, Nova Scotia
B3S 1N2 Canada
Phone: (902) 429-1200
Fax: (902) 484-5583
Contact: Craig Fraser, VP of Sales and Product Management

2. Submission Correspondent

Emergo Group, Inc.
816 Congress Avenue, Suite 1400
Austin, TX 78701
Cell Phone: (561) 305-5075
Office Phone: (512) 327-9997
Fax: (512) 327-9998
Contact: Diane Sudduth, Senior Consultant, QA
Email: project.management@emergogroup.com

3. Date Prepared

May 2, 2013

4. Device Identification

Trade/Proprietary Name:	Medusa Medical Technologies, Inc. Siren ePCR Suite™
Common/Usual Name:	Siren ePCR
Classification Name:	Display, Cathode Ray Tube, Medical
Classification Regulation:	870.2450
Product Code:	DXJ; NSX
Device Class:	Class II
Classification Panel:	Cardiovascular; General Hospital

5. Predicate Devices

K103473 Zoll Medical Corporation - RescueNet ePCR

6. Device Description

Siren ePCR Suite™ is a software-only product. Siren ePCR Suite™ is a medical data collection system used to collect, store and print patient data that is entered by a user (caregiver), or captured from specified medical devices, and is integrated into a patient care report (patient

electronic medical record). Siren ePCR Suite™ is non-alarming software that runs on a variety of commercial off-the-shelf hardware.

7. Intended Use

Siren ePCR Suite™ is intended for the collection, storage and printing of patient data that is entered by a user (paramedics), or captured from specified medical devices, and integrated into a patient care report (patient electronic medical record). Siren ePCR Suite™ is intended for use by qualified medical personnel providing direct patient care in the pre-hospital environment to document the care provided. Siren ePCR Suite™ is indicated for use by health care providers whenever there is a need for generation of a patient record.

8. Comparison of Technological Characteristics

The following table compares the Siren ePCR Suite™ to the predicate device with respect to intended use, overall technological and functional characteristics, providing more detailed information regarding the basis for the determination of substantial equivalence.

The Siren ePCR Suite™ is similar in design and function to the predicate device for the modes of operation and use.

Table 5A – Comparison of Characteristics

Manufacturer	**Zoll Medical Corporation**	**Medusa Medical Technologies Inc.**
Trade Name	Predicate RescueNet ePCR	New Device Siren ePCR Suite™
510(k) Number	**K103473**	**Not assigned**
Product Code	**DJX** NSX	**DJX** **NSX**
Regulation Number	870.2450 Null	870.2450 Null
Regulation Name	**Display, Cathode Ray Tube, Medical** Software, Transmission and Storage, Patient Data	**Display, Cathode Ray Tube, Medical** Software, Transmission and Storage, Patient Data
Indications for Use	RescueNet ePCR is intended for the collection, storage and printing of patient data that is entered by a user (caregiver), or captured from specified medical devices, and integrated into a patient care report (patient electronic medical record).	Siren ePCR Suite™ is intended for the collection, storage and printing of patient data that is entered by a user (paramedic), or captured from specified medical devices, and integrated into a patient care report (patient electronic medical

Manufacturer	**Zoll Medical Corporation**	**Medusa Medical Technologies Inc.**
Trade Name	Predicate RescueNet ePCR	New Device Siren ePCR Suite™
	RescueNet ePCR is intended for use by qualified medical personnel providing direct patient care in the pre-hospital environment to document the care provided. RescueNet ePCR is indicated for use by health care providers whenever there is a need for generation of a patient record.	record). Siren ePCR Suite™ is intended for use by qualified medical personnel providing direct patient care in the pre-hospital environment to document the care provided. Siren ePCR Suite™ is indicated for use by health care providers whenever there is a need for generation of a patient record.
Material	Software	Software
System Requirements		
Compatible operating system (software only)	Windows XP Professional	Field User: Windows XP or XP Tablet Edition SP3 or Windows 7 SP1; SQL Express 2005 SP3 Server: Windows Server 2003 R2 SP3; SQL Server 2005 SP3 / SQL Server 2008 SP3 .NET Framework
Web-Based Application (Locally installed vs. vendor server based)	WebPCR module provides a web based access when connected to web browser or WebPCR server.	Web based Administration and Workflow. Store and forward communication from tablet to server.
Hardware		
Compatibility and system requirements		
Desktop PC	Yes	Yes
Tablet PC	Yes	Yes
Pocket PC/Palm device compatible	Yes	No
Internet connection required at all time or only during data sync	Only during data sync from mobile devices	Only during data sync from mobile devices
Printer compatibility	Yes, can print locally or across a network	Yes, can print locally or across a network
Wireless access supported (ie Verizon/sprint WWAN)	Yes	Yes

Manufacturer	**Zoll Medical Corporation**	**Medusa Medical Technologies Inc.**
Trade Name	Predicate RescueNet ePCR	New Device Siren ePCR Suite™
Security		
Data encryption	Yes	Yes
Ability to lock PCR once completed	Yes	Yes
Tracks changes to module databases, including date, time, computer and user who made the change	Yes	Yes
Data Exchange		
Interface to server (Data synchronization)	Yes, wireless or hard wired	Over internet connection
Interface with CAD/Dispatch	Yes	Yes
Interface with Hospitals (Fax, email/etc., direct sync, etc.)	Yes	Yes
Interface with Hospital Pre-Alert	Yes	Yes
Interface with Billing	Yes	Yes
Interface with Medical Equipment	Physio-Control LifePak 11 monitor/defibrillator, LifePak 12/15 monitor/defibrillator, LifePak 500 monitor/defibrillator; Philips HeartStart MRx; Zoll 1600, AED Plus/AED Pro, M Series/E Series	Physio-Control LifePak 12/15 monitor/defibrillator Philips HeartStart MRx Zoll M Series/E Series
EKG Integration	Yes	Yes
Mobile-to-mobile data transfer	Yes	Yes
Interfaces to electronic record (EHR) / HL7	Yes	Yes

Manufacturer	**Zoll Medical Corporation**	**Medusa Medical Technologies Inc.**
Trade Name	Predicate RescueNet ePCR	New Device Siren ePCR Suite™
Additional Features		
Electronic Signature Support	Yes	Yes
Ability to link reference documents (protocols)	Yes	Yes
Ability to populate patient info from previous patient contact	Yes	Yes
Drug Monograph database	No	Yes via integration with existing commercial drug monograph providers (MicroMedix)
Use environment	EMT, paramedic	EMT, paramedic
Intended users (target population)	Professional Users	Professional Users

9. Non-Clinical Testing

The device's software development, verification and validation have been carried out in accordance with the FDA's guidance documents. The software was tested against the established Software Design Specifications for each of the test plans to assure the device performs as intended.

The device Hazard analysis was completed and risk control implemented to mitigate hazards. The testing results supports that all specifications have met the acceptance criteria of each module and interaction of processes. Siren ePCR Suite™ device passed all testing and supports the claims of substantial equivalence and safe operation.

10. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a new device is substantially equivalent to a predicate device when the device has the same intended use as the previously cleared predicate device and either (i) the same technological characteristics as the predicate, or (ii) if the new device has different

technological characteristics, then those differences raise no new issues regarding the safety or effectiveness of the new device.

It has been shown in this 510(k) submission that Siren ePCR Suite™ has the same intended use as the predicate device and that any technological differences between the Siren ePCR Suite™ software and the predicate device do not raise any questions regarding Siren ePCR Suite™'s safety and effectiveness. Performance testing and compliance with voluntary standards demonstrate that Siren ePCR Suite™ software is substantially equivalent to the relevant aspects of the predicate device in terms of design, principals of operation, performance characteristics, and intended use. The Siren ePCR Suite™ software, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate devices.