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

April 30, 2015

Sotera Wireless, Inc.
Carson Krupp
Product Risk Assurance Engineer
10020 Huennekens Street
San Diego, California 92121

Re: K150361
Trade/Device Name: ViSi Mobile Monitoring System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DRT, DXN, FLL, DQA
Dated: April 1, 2015
Received: April 2, 2015

Dear Carson Krupp:

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.

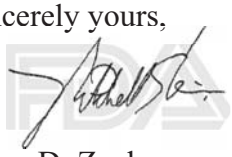
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,



forBram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150361

Device Name
ViSi Mobile Monitoring System

Indications for Use *(Describe)*
The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult patients (18 years or older). It is indicated for ECG (3 or 5 lead-wire), respiration rate (RESP), heart rate (HR), noninvasive blood pressure (NIBP), continuous noninvasive blood pressure (cNIBP), noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), and skin temperature (TEMP) in hospital-based facilities; including, general medical-surgical floors, intermediate care floors, and emergency departments.

The ViSi Mobile Monitoring System may be used as standalone devices or networked to ViSi Mobile Remote Viewers through wireless 802.11 communication.

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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7 510(K) SUMMARY

Date prepared	March 25, 2015
Name	Sotera Wireless, Inc. 10020 Huennekens St San Diego, CA 92121 T. 858.427.4620; F. 858.999.2487
Trade name	ViSi Mobile Monitoring System
Common name	Vital signs monitor
Regulation Name	Cardiac Monitor Including Cardiotachometer and Rate Alarm
Classification number	21 CFR 870.2300
Product code	MWI, DRT, DXN, DQA, FLL
Regulatory class	II
Predicate devices	ViSi Mobile Monitoring System; K143751 (Clearance: 01/23/2015)
Description	The ViSi Mobile Monitoring System is a lightweight, body-worn vital signs monitor featuring a high resolution, full color touch screen display, with visual and audible alarms and alerts. The ViSi Mobile Monitor is designed to continuously non-invasively measure ECG, heart rate, SpO2, blood pressure, pulse rate, respiration rate, and temperature. The ECG, SpO2, and Respiration waveforms are viewable on demand. The ViSi Mobile Monitoring System is capable of one-time and continuous NIBP measurements.
Indications for use	The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult patients (18 years or older). It is indicated for ECG (3 or 5 lead-wire), respiration rate (RESP), heart rate (HR), noninvasive blood pressure (NIBP), continuous noninvasive blood pressure (cNIBP), noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), and skin temperature (TEMP) in hospital-based facilities; including, general medical-surgical floors, intermediate care floors, and emergency departments. The ViSi Mobile Monitoring System may be used as standalone devices or networked to ViSi Mobile Remote Viewers through wireless 802.11 communication.

Substantial Equivalence Table

Device	**Modified ViSi System w/Posture Feature Set [510(k) TBD]**	**ViSi System Predicate (K143751)**
Manufacturer	Same as ViSi System (Predicate)	Sotera Wireless, Inc.
Intended Use	Same as ViSi System (Predicate)	The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult patients (18 years or older). It is indicated for ECG (3 or 5 lead-wire), respiration rate (RESP), heart rate (HR), noninvasive blood pressure (NIBP), continuous noninvasive blood pressure (cNIBP), noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), and skin temperature (TEMP) in hospital-based facilities; including, general medical-surgical floors, intermediate care floors, and emergency departments. The ViSi Mobile Monitoring System may be used as standalone devices or networked to ViSi Mobile Remote Viewers through wireless 802.11 communication.
Parameters monitored and displayed	Same as ViSi System (Predicate)	Electrocardiogram (ECG), respiration rate, blood oxygen saturation (SpO2), non-invasive blood pressure (NIBP), continuous noninvasive blood pressure (cNIBP), pulse rate, heart rate, temperature
Posture Tracking	Posture (standing/sitting-up, reclined, supine) is displayed on the RVD / PWD and required to set-up cNIBP. *Patient Walking can be displayed. Alarm features annunciate on undesirable postures, immobility and patient falls.*	Posture (standing/sitting-up, reclined, supine) is displayed on the RVD / PWD and required to set-up cNIBP.
Patient population	Same as ViSi System (Predicate)	Adults ≥ 18 years
Environment of Use	Same as ViSi System (Predicate)	Hospital-based facility including emergency departments, general medical-surgical and intermediate care floors.
System Design	Same as ViSi System (Predicate)	Patient monitor displays vital signs and waveforms. Communicates to server via wireless access point. Server is hardwired to display PC.
ECG Leads	Same as ViSi System (Predicate)	3-wire: II 5-wire: I, II, III, AVL, AVR, AVF, V
Radio Frequency Telemetry	Same as ViSi System (Predicate)	802.11
Alarm Annunciation	Same as ViSi System (Predicate)	Monitor, Central Station (server-connected PC)
Alarm levels/mgmt. connected/linked	Same as ViSi System (Predicate)	Vital Signs

Summary of substantial equivalence

The device design, technology, materials, processes, etc. have not been changed with this application. The modifications were to add the following posture alarm features: (1) undesirable posture technical alarm, (2) patient immobility technical alarm, and (3) patient fall alarm. (4) The last modification allows the system to display if the patient is walking along with the already existing ability to display if a patient is upright, reclined or lying-down. This modification is purely a visual icon and has no associated alarms. All four modifications were implemented to provide clinicians with information that will increase patient safety.

Non-clinical performance (verification and validation) testing of the aforementioned features was completed to confirm that the features, as implemented, met all requirements. Verification testing included code reviews, static testing and algorithm monitoring to ensure it performed as intended. Design validation testing consisted of the following tests:

- Code Reviews, Static Testing, Unit Testing
- SVT-000061 – Walking Algorithm Software Verification
- SVT-000062 – Undesirable Posture, Immobility and Fall Detection Software verification
- TP-670 – Undesirable Posture Alarms Validation
- TP-671 – Immobility Alarms Validation
- TP-672 – Patient Fall Alarm Validation
- TP-673 – Posture Definitions and Walking Validation

The results demonstrated that all acceptance criteria were met, and therefore conforms to expected device performance and intended use.

Therefore the ViSi Mobile Monitoring System is as safe, as effective, and performs as well as or better than the legally marketed predicate device.