



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 14, 2015

Sotera Wireless, Inc
% Mark Job
Official Correspondent
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K152341

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, DQA, FLL, MSX
Dated: October 21, 2015
Received: October 22, 2015

Dear Mark Job:

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

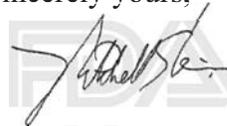
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go 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,



for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152341

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.

The ViSi Mobile InSight is an optional secondary notification system that communicates alarms directly to an assigned caregiver. It is intended to supplement the primary alarming devices which originate in the ViSi Mobile patient worn device.

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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6 510(K) SUMMARY

| | |
|-----------------------------|---|
| Date prepared | December 11, 2015 |
| Name | Sotera Wireless, Inc. 10020 Huennekens St San Diego, CA 92121 T. 858.427.4620; F. 858.999.2487 |
| Contact Name | Carson Krupp |
| 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 |
| Classification Product Code | MWI |
| Subsequent Product Codes | DRT, DXN, DQA, FLL, MSX |
| Regulatory class | II |
| Predicate devices | ViSi Mobile Monitoring System; K143751 (Clearance: 01/23/2015) EXTENSION Clinical Alert Notification System; K130339 (Clearance: 07/11/2013) |
| 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.

The ViSi Mobile InSight is an optional secondary notification system that communicates alarms directly to an assigned caregiver. It is intended to supplement the primary alarming devices which originate in the ViSi Mobile patient worn device.

Summary of Substantial Equivalence

The previously cleared (K143751) ViSi Mobile Monitoring System (“ViSi System”) distributed alarming system has been modified to allow an assigned-caregiver-response with respect to annunciated alarms through the utilization of ViSi Mobile InSight. Previously, the Patient Data Server (PDS) would only distribute alarm notifications to the Remote Viewing Device (RVD). From the RVD, an operator could confirm receipt of the alarm through the use of an “Acknowledgement.” In the modified system, the PDS will still send the alarm to the RVD and will also secondarily distribute the alarm notifications to assigned caregivers on network-connected mobile devices configured with ViSi Mobile InSight. Once received, the operator will be able to “Accept” or “Decline” the alarm. Accepting the alarm will silence the annunciation on both the mobile device and the RVD, albeit temporarily, and declining the alarm will redirect the annunciation to the next operator in a predefined pathway. In both cases, the response will constitute a confirmed delivery of the alarm notification.

The user response and redirection pathway functionality described above for the ViSi System with ViSi Mobile InSight is similar to that of EXTENSION’s Clinical Alert Notification System (K130339) in that both provide a secondary means of alarming for patients on configurable mobile devices in which the user can “Accept” or “Decline” alarms, the latter initiating an alarm redirection pathway. However, EXTENSION’s system is on a closed-loop and does not directly interact with the monitoring system supplying the alarms.

The ViSi Mobile Monitoring System with ViSi Mobile InSight will provide an end-to-end solution for distributed alarms. That is, alarms originating from the patient worn device are communicated through the ViSi Mobile PDS to a mobile device carried by a caregiver assigned to the patient. The caregiver can accept the alarm (which effectively silences it) or redirect the alarm to another caregiver by declining or ignoring.

The risk analysis determined that the risk for the ViSi System is not appreciably altered by the implementation of the additional features and is intended to provide medical personnel with information that will have a positive effect on patient safety by integrating alarm notification into their routine work-flow. The risk analysis concluded that the benefits in overall patient safety outweighed the risks and therefore the implementation of ViSi Mobile InSight is worthwhile.

The ViSi System’s device design, technology, materials, processes, etc. have not been changed with this application. The modification is only to add the aforementioned ViSi Mobile InSight capability to the intended use; therefore the

ViSi Mobile Monitoring System as described in this submission is substantially equivalent to the predicate ViSi System (K143751).

Summary of
Performance Testing

Non-Clinical Performance Testing of ViSi Mobile InSight was done in three phases – Human Factors testing, verification testing and validation testing. Human factors testing was completed to assess both the usability and readability of ViSi Mobile InSight. For the testing, clinicians already familiar with the ViSi Mobile System but not ViSi Mobile InSight were asked to answer a series of questions and to perform a series of interactive tasks. The testing was proctored by Sotera employees and utilized simulators to announce alarms; no patients were used as a part of this testing. At the conclusion of the questions/tasks, each participant was interviewed to provide feedback on ViSi Mobile InSight. Overall, the results of the testing satisfied the defined acceptance criteria and validated that proper human factors design was used in the development of ViSi Mobile InSight.

Verification activities included the completion of code reviews and unit testing. Unit tests were completed on both software components of ViSi Mobile InSight by sending mock-up data into methods and checking the output of these methods against the expected output. These tests were performed for each build compiled and the results all passed.

Validation testing was completed to ensure that all software requirements were met and performed as intended. All test steps within the validation protocol passed.

Performance testing was also completed in an intended-use hospital environment with the primary ViSi System under full-load (64 ViSi Wrist Transceivers connected to the RVD/PDS) to characterize alarm receipt and alarm latency periods for the ViSi InSight secondary alarm notification system.