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 23, 2015

Sotera Wireless, Inc.
% Mark Job
Regulatory Technology Services, LLC
1394 25th Street, Nw
Buffalo, Minnesota 55313

Re: K143751
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
Dated: December 30, 2014
Received: December 31, 2014

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,

Melissa A. Torres -S

For Bram 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 on last page.

510(k) Number *(if known)*

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), non-invasive blood pressure (NIBP), continuous noninvasive blood pressure (cNIBP), non-invasive 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

5 510(K) SUMMARY

Date prepared	November 13, 2014
Name	Sotera Wireless, Inc. 10020 Huennekens Street 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; K133586 (Clearance: 12/18/2013) ViSi Mobile Monitoring System; K130709 (Clearance: 10/7/2013)
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), non-invasive blood pressure (NIBP), continuous non-invasive blood pressure (cNIBP), non-invasive 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.
Summary of	The device design, technology, materials, processes, etc. have not been

substantial equivalence	changed with this application. The modifications are: (1) to add the previously cleared cNIBP Indication for Use to the previously cleared networked ViSi Mobile Monitoring System and (2) to improve QRS detection across a wide range of ECG waveform morphologies to reduce the cases where noise on the ECG waveform is prohibiting the recognition of a QRS complex. Non-clinical performance testing of the new ECG beat-picker demonstrated equal to or better performance than the prior beat-picker on the MIT and AHA databases in terms of gross Q sensitivity and gross Q positive predictivity for the AHA database with a negligible reduction in gross Q positive predictivity for the MIT set. Given the overall result it was determined that there was an improvement of performance over the existing algorithm. Conformance to IEC 60601-2-27 was also demonstrated. Therefore the ViSi Mobile Monitoring System is as safe, as effective, and performs as well as or better than the legally marketed predicate devices.