Sotera WIRELESS

8 510(K) SUMMARY

DEC 18 2013

Date prepared	November 20, 2013
Name	Sotera Wireless, Inc. 9444 Waples Street, Suite 280 San Diego, CA 92121 T. 858.373:4841; F. 858.427.4639
Contact person	Eben Gordon Senior Director, Regulatory
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; K122036 (Clearance: 8/18/2012)
Description	The ViSi Mobile Monitoring System is a lightweight, portable patient vital signs monitor featuring a high resolution, full color touch screen display, with visual and audible alarms and alerts. The ViSi Mobile Monitor is body-worn and designed to continuously measure ECG, heart rate, SpO2, pulse rate, respiration rate, and temperature. The ECG, SpO2, and Respiration waveforms are viewable on demand. NIBP can be measured as a onetime measurement, or it can be measured automatically at predefined intervals
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. It is indicated for ECG (3 or 5 leadwire), respiration rate (RESP), heart rate (HR), non-invasive blood pressure (NIBP), 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 central station through wireless 802.11 communication.
Summary of substantial equivalence	The device design, technology, materials, processes, etc. have not been changed with this application. The modification is only to increase the time to alarm for critically low, low, and high heart rates; therefore the ViSi Mobile Monitoring System as described in this submission is substantially equivalent to the predicate device.

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

December 18, 2013

Sotera Wireless, Inc.
Eben Gordon
Senior Director, Regulatory
9444 Waples Street Suite 280
San Diego, CA 92121 US

Re: K133586
Trade/Device Name: Visi Mobile Monitioring System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II (two)
Product Code: MWI, DRT, DXN, DQA, FLL
Dated: November 20, 2013
Received: November 21, 2013

Dear Eben Gordon:

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" (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 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,

Owen D. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

7 INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: _____ ViSi Mobile Monitoring System _____

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. It is indicated for ECG (3 or 5 leadwire), respiration rate (RESP), heart rate (HR), non-invasive blood pressure (NIBP), 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 central station through wireless 802.11 communication.

Prescription Use ___X____ AND/OR Over the Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen R. Faris -S
Date: 2018.12.18 14:00:10 -05'00'

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