Sotera WIRELESS

510(k) Summary

Date prepared	November 20, 2011
Name	Sotera Wireless, Inc. 9444 Waples Street, Suite 280 San Diego, CA 92121 T. 858.427.4620; F. 858.427.4639
Contact person	Eben Gordon Senior Director, Regulatory
Trade name	ViSi Mobile Monitoring System
Common name	Vital signs monitor
Classification name	Cardiac monitor (including cardiotachometer and rate alarm)
Classification regulation	Monitor, physiological, patient(without arrhythmia detection or alarms; 21 CFR 870.2300 (MWI)
Predicate device	Nihon Kohden ZS-940PA K043517, Clearance date: February 3, 2005 Omron Healthcare, Inc., HBP-2070 K082812, Clearance date: October 22, 2008
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.
Summary of substantial equivalence	The ViSi System has the following similarities and differences with the indicated predicate devices: • Intended use – The ViSi System and the predicate devices have the same intended uses as the predicate devices: vital signs monitoring.

- Technology – The ViSi System has the same technological characteristics as the predicate devices in terms of SpO2, ECG, HR, PR, and respiration.

  While NIBP is measured using oscillation for all three devices, the ViSi System determines blood pressure on inflation rather than deflation. The validity of this method was confirmed in an ISO 81060-2 compliant clinical study demonstrating that this method of blood pressure meets the requirements of the standard in terms of accuracy and variability.

  The Nihon Kohden device has the capability to transmit data wirelessly in addition to local display and alarming while the ViSi System differs in that it only has the capability to display and alarm locally (i.e. does not transmit data wirelessly). Similar to the Omron HBP-2070, the ViSi does not transmit data for remote viewing.

- Design - ViSi System and the Nihon Kohden ZS-940PA have similar form factors in that they both are patient worn. The Omron HBP-2070 is not attached to the patient.

  The safety and effectiveness of the design elements implemented into the ViSi System have been confirmed by their compliance to the prevailing vital signs monitoring standards. The ViSi System has demonstrated compliance with the applicable sections of the following consensus standards: IEC 60601-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-1-8, IEC 60601-2-27, IEC 60601-2-49, IEC 80601-2-30, ISO 9919, ASTM E1112, EC13, and EC53.

- General Safety and Effectiveness Concerns – The instructions for use for the ViSi System contains the necessary cautions and warnings to provide for safe and effective use of the device.

  The ViSi System has successfully undergone safety testing as well as functional testing to demonstrate equivalence to the predicate devices. The following quality assurance measures were applied to the device: Risk analysis, Requirements review, Code inspections, Verification and validation, Bench testing, Clinical performance testing, Biocompatibility testing, and Safety testing

The ViSi System have been tested and found to comply with recognized national and international performance, safety, and electromagnetic compatibility standards for medical devices. The results of all the testing demonstrate that the ViSi System is safe, effective, complies with the appropriate medical device standards, and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

MAR 2 2 2012

Sotera Wireless, Inc.
c/o Mr. Eben Gordon
Sr. Director, Regulatory Affairs
9444 Waples St., Suite 280
San Diego, CA 92121

Re: K112478
Trade/Device Names: Visi Mobile Monitoring System, Model (H1,1a)
Regulatory 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 and FLL
Dated: March 2, 2012
Received: March 5, 2012

Dear Mr. 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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

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

Enclosure

4 INDICATIONS FOR USE

510(k) Number (if known): K112478

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.

Prescription Use ___X____ AND/OR Over the Counter Use _____

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices

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