June 19, 2018

Sotera Wireless, Inc.
Frank Pokrop
Senior Director, Regulatory Affairs and Quality
10020 Huenneckens Street
San Diego, California 92121

Re: K180472
Trade/Device Name: ViSi Mobile Monitoring System
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including ST-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: MHX, DSI, DRT, DXN, DQA, FLL
Dated: May 16, 2018
Received: May 17, 2018

Dear Frank Pokrop:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180472

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), skin temperature (TEMP), posture tracking and alarms, and basic arrhythmia (Ventricular Tachycardia, Ventricular Fibrillation, Asystole, Atrial Fibrillation) analysis and alarm in hospital-based facilities including general medical-surgical floors, intermediate care floors, and emergency departments.

Continuous non-invasive blood pressure (cNIBP) measurements have not been evaluated on patients during ambulation. The basic arrhythmia analysis feature is intended for use on patients 18 years of age and older; it has not been evaluated on pediatric patients.

The arrhythmia analysis feature is intended for use by healthcare professionals trained in the identification and treatment of arrhythmia events. Automated arrhythmia analysis is an adjunct to clinical assessment; clinician review of the analysis should precede any therapeutic intervention.

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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SECTION 5. 510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92), the 510(k) Summary for the ViSi Mobile Monitoring System is provided below:

Submitter Information

Date prepared	June 15, 2018
Name	Sotera Wireless, Inc.
	10020 Huennekens Street
	San Diego, CA 92121
Contact Person	Frank Pokrop
	Sr. Director, Regulatory Affairs and Quality

Device Identification

Trade name	ViSi Mobile Monitoring System
Common name	Vital signs monitor
Regulation Name	Monitor, physiological, patient (with arrhythmia detection or alarms)
Classification number	21 CFR 870.1025
Product code	MHX, DSI, DRT, DXN, DQA, FLL
Regulatory class	II
Predicate devices	ViSi Mobile Monitoring System; K152341
Reference devices	ViSi Mobile Monitoring System; K142827, K150361

Description

The ViSi Mobile Monitoring System is a patient worn, portable, battery operated, continuous physiological monitoring device intended for the monitoring of 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), skin temperature (SKIN TEMP), posture tracking and alarms, basic arrhythmia analysis (ventricular fibrillation, ventricular tachycardia, asystole, atrial fibrillation) and alarms.

The ViSi Mobile Monitoring System consists of the patient worn devices, disposables, backup battery, patient data server and remote viewer.

Intended 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), skin temperature (TEMP), posture tracking and alarms, and basic arrhythmia (Ventricular Tachycardia, Ventricular Fibrillation, Asystole, Atrial Fibrillation) analysis and alarm in hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency departments.

Continuous non-invasive blood pressure (cNIBP) measurements have not been evaluated on patients during ambulation.

The basic arrhythmia analysis feature is intended for use on patients 18 years of age and older; it has not been evaluated on pediatric patients.

The arrhythmia analysis feature is intended for use by healthcare professionals trained in the identification and treatment of arrhythmia events. Automated arrhythmia analysis is an adjunct to clinical assessment; clinician review of the analysis should precede any therapeutic intervention.

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.

Comparison with the Predicate Device [21CFR807.92(a)(6)] table below demonstrates that the proposed ViSi Mobile Monitoring System is comparable with and substantially equivalent to the predicate device, cleared under 510(k) #: K152341.

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Technical Characteristics Comparison:

The basic and main technical features of the modified ViSi Mobile Monitoring System are the same as the predicate device including Design, Operation Control, Display Modes, and Performance Results.

I. Table #1. General Comparison

Characteristic	Comparison or Comment	ViSi Mobile Monitoring System (TBD)	ViSi Mobile Monitoring System (K152341)
		Proposed Device	Predicate Device
Manufacturer	Same	Sotera Wireless, Inc.	Sotera Wireless, Inc.
Product Codes	Same	MHX, DSI, DRT, DXN, DQA, FLL	MHX, DSI, DRT, DXN, DQA, FLL
Classification	Same	2	2
Classification Regulation	Same	870.1025	870.1025
Intended Use	Same and Similar Proposed device contains arrhythmia analysis	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	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

Characteristic	Comparison or Comment	ViSi Mobile Monitoring System (TBD)	ViSi Mobile Monitoring System (K152341)
		Proposed Device	**Predicate Device**
		(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), posture tracking and alarms, skin temperature (TEMP) and basic arrhythmia (Ventricular Tachycardia, Ventricular Fibrillation, Asystole, Atrial Fibrillation) analysis/alarm in hospital-based facilities; including, general medical-surgical floors, intermediate care floors, and emergency departments. Continuous non-invasive blood pressure (cNIBP) measurements have not been evaluated on patients during ambulation. The arrhythmia analysis feature is intended for use by healthcare professionals trained in the identification and treatment of	(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.

Characteristic	Comparison or Comment	ViSi Mobile Monitoring System (TBD)	ViSi Mobile Monitoring System (K152341)
		Proposed Device	**Predicate Device**
		arrhythmia events. Automated arrhythmia analysis is an adjunct to clinical assessment; clinician review of the analysis should precede any therapeutic intervention.	
Use of ViSi Mobile Insight	Same	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.	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.
Remote Viewing	Same	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 Monitoring System may be used as standalone devices or networked to ViSi Mobile Remote Viewers through wireless 802.11 communication.
Patient Population	Same	18 years or older	18 years or older
Environment of Use	Same	Hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency	Hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency

Characteristic	Comparison or Comment	ViSi Mobile Monitoring System (TBD)	ViSi Mobile Monitoring System (K152341)
		Proposed Device	**Predicate Device**
		departments	departments
Auto Set Feature	Similar	Auto Set features are enabled for BP MAP parameter.	Auto Set Feature present in K152341 and earlier models
	Expanded	Heart Rate and Pulse Rate default patient limits were changed to Low 30, High 150	Heart Rate and Pulse Rate default patient limits were Low: 40, High 140
Patient Postures	Expanded	Patient Walking – previously part of prior products now an individually set feature. Recline left and recline right added.	Patient Walking – previously included in undesirable posture features. Cleared in reference device, 510(k) #: K150361.
Arrhythmia Detection Algorithm	Similar	Rewritten to improve specificity and detection metrics	Cleared in reference device, 510(k) #: K14827.
(1) Software Changes - *General*	Expanded	Software was enhanced and expanded covering both normal refinements and specific additions and improvements.	510(k) #: K152341 included various software features as shown in the submission and indications for use.
(2) Software Changes – *Specific*	Expanded as Shown Below:	*Additional* Project-Specific Features are Detailed Below - **Apollo Project (Software Version 3.x.x)**	
	a) ViSi Access	Ability to access "Vital Sign" display on the Monitor without entering a Pin Code	Not present – or improved

Characteristic	Comparison or Comment	ViSi Mobile Monitoring System (TBD) Proposed Device	ViSi Mobile Monitoring System (K152341) Predicate Device
	b) Session Management including a change to the Device Swap Method	• Improved Pause / Stop Monitoring Flows to eliminate the need to complete a physical *Bump* for Device Swap when the Monitor battery is low • Ability to Assign and confirm the patient demographics for a new/resumed monitoring session directly from the Wrist Monitor	Not present – or improved
	c) cNIBP Updates	• cNIBP calibration alert was divided into three different, more informative alerts • cNIBP calibration and data carry-over after device swap within 10 minutes of device pause and resume	Not present – or improved
	d) Multiple Care Units	• Ability to display/configure multiple Care Units from the same server (PDS) • Ability to assign a Care unit from the Wrist Monitor when starting a new monitoring session • Ability to transfer the patient from one care unit to another using the same Monitor	Not present – or improved

Characteristic	Comparison or Comment	ViSi Mobile Monitoring System (TBD)	ViSi Mobile Monitoring System (K152341)
		Proposed Device	**Predicate Device**
		• Ability to associate room/bed locations from multiple care units to Remote Viewer • Care Unit Room/bed locations can either be "pinned" to a specific placeholder on the RVD or remain "unpinned" and allow the clinician to place the active session in any desired location.	
	e) Remote Viewer Graphic User Interface (GUI) Enhancements	• Updated GUI for the patient workspace header to be consistent across all screens • Improved vital sign alarm limits data entry • Enhanced Current Waveforms display • Enhanced Graphical Trends display • Enhanced List Trends display • Devices workspace which displays current battery life of all active Monitors • Ability to print patient list trends in specific date/time ranges.	Not present – or improved
	f) Miscellaneo	• Improved handling of alarms/alerts	Not present – or improved

Characteristic	Comparison or Comment	ViSi Mobile Monitoring System (TBD) Proposed Device	ViSi Mobile Monitoring System (K152341) Predicate Device
	us Enhancements	when the device goes in and out of network • Improved Power Pack indicators (when connected to Wrist Monitor) • Updated icon for "Battery Too Hot" • Alarm acknowledgement time increased from 2 minutes to 10 minutes • Extended annunciation delay for "Network Lost" alert • Added ability to set-up "Read-only" RVDs which reduce the amount of visible patient health information and do not allow interactions other than viewing patient sessions	
(3) Software Changes – *Specific*	Expanded as Shown Below:	*Additional* Project-Specific Features are Detailed Below - **Bacchus Project (Software Version 4.0.x)**	
	a) Arrhythmia Analysis Algorithm	• New arrhythmia detection algorithm to improve arrhythmia detection accuracy and positive predictivity	Not present – or improved
	b) Patient Posture	• Add two new postures (reclined right-side and reclined left-side), and icons to display "Immobility/Reclined Right Side",	Not present – or improved

Characteristic	Comparison or Comment	ViSi Mobile Monitoring System (TBD)	ViSi Mobile Monitoring System (K152341)
		Proposed Device	**Predicate Device**
		and Immobility/Reclined Left Side" posture status, and alert icons "Undesired + Immobility)/Reclined Right Side" and "Undesired + Immobility)/Reclined Left Side" • "Undesired/Walking" alert text changed to "PATIENT WALKING" Alert	
	c) Other Changes	• Updated the algorithm that generates a "Check Thumb Sensor" alert to identify non-functioning thumb sensors and added new alert text ("Swap Thumb Sensor") to signify when this occurs. "Check Thumb Sensor" will remain to indicate that the sensor is either off the patient or not positioned properly. • SW Versioning check and alert to convey that the accessory (i.e., ECG Cable, NIBP Module or Power Pack) is not compatible with the Wrist Monitor	Not present – or improved
Hardware Changes and Enhancements	Changed and Improved	• Li-ion power pack • NIBP cuffs • NIBP cuff adapters	Not present – or improved

Characteristic	Comparison or Comment	ViSi Mobile Monitoring System (TBD)	ViSi Mobile Monitoring System (K152341)
		Proposed Device	**Predicate Device**
		• Thumb tape • 5GHz band for dual band wireless radio	

II. Table #2. Comparison of Technical Performance Features

---- Technical Performance Features ---			
Characteristic	**Comment and Comparison**	**ViSi Mobile Monitoring System (TBD)**	**ViSi Mobile Monitoring System (K152341)**
		Proposed Device	**Predicate Device**
Waveform Data	Same	ECG, SpO2, Respiration, cNIBP	ECG, SpO2, Respiration, cNIBP
Wrist Monitor Connectivity	Same	Standalone or Wireless	Standalone or Wireless
Network Connectivity	Same	802.11a/b/g/n	802.11a/b/g/n
Wrist Monitor Display	Same	Internal OLED Display	Internal OLED Display
Energy Type and Source	Same	Lithium ion battery	Lithium ion battery
EMC Compliance	Same	IEC 60601-1-2	IEC 60601-1-2
Product Safety	Same	IEC 60601-1	IEC 60601-1
Operating Temperature	Same	0 - 50°C	0 - 50°C
Operation Humidity	Same	15 – 95% non-condensing	15 – 95% non-condensing

---- Technical Performance Features ---			
Characteristic	**Comment and Comparison**	**ViSi Mobile Monitoring System (TBD)**	**ViSi Mobile Monitoring System (K152341)**
		Proposed Device	**Predicate Device**
Operating Pressure	Same	106 kPa – 70 kPa	106 kPa – 70 kPa

III. Table #3. Discussion and Comparison of Predicate and Reference Devices

---- Discussion and Comparison of Predicate and Reference Devices ---					
Comment and Comparison	**Characteristic**	**Proposed Device**	**Predicate Device 510(k) #: 152341**	Reference Device 510k#: 150361	Reference Device 510k#: 142827
Same	**Manufacturer**	Sotera Wireless, Inc.	Sotera Wireless, Inc.	Sotera Wireless, Inc.	Sotera Wireless, Inc.
Same	**Product Codes**	MHX, DSI, DRT, DXN, DQA, FLL	MHX, DSI, DRT, DXN, DQA, FLL	MHX, DSI, DRT, DXN, DQA, FLL	MHX, DSI, DRT, DXN, DQA, FLL
Same	**Classification**	2	2	2	2
Same	**Classification Regulation**	870.1025	870.1025	870.2300	870.1025
Same	**Auto Set Feature – *Presence***	Same	Same	Same	Same
Expanded	**Auto Set Feature *Expanded Limits***	Expanded Limits	Present	Present	Present
Same	**Patient Population**	18 years or older	Same	Same	Same
Same	**Technical Operating Principles and Uses**	Same	Same	Same	Same

---- Discussion and Comparison of Predicate and Reference Devices ---

Comment and Comparison	Characteristic	Proposed Device	Predicate Device 510(k) #: 152341	Reference Device 510k#: 150361	Reference Device 510k#: 142827
	Environments as Described in the Table Above				
Expanded	**Communications**	Dual Band	Single Band	Single Band	Single Band
Same or similar	**Patient Postures**	Enhanced	N/A	N/A	Present
Same or similar	**Arrythmia**	Enhanced		Present	
Expanded	**Components**	Allows for the use of competitive components	Components required but exclusive to Sotera		
Same	**Use Environment** Hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency departments	Same	Same	Same	Same

---- Discussion and Comparison of Predicate and Reference Devices ---

Comment and Comparison	Characteristic	Proposed Device	Predicate Device 510(k) #: 152341	Reference Device 510k#: 150361	Reference Device 510k#: 142827
Same and Similar But Expanded Over Time	**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	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	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	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), arrhythmia analysis, respiration rate, heart rate, non-invasive blood pressure (NIBP), continuous non-invasive blood pressure (cNIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, and skin temperature in hospital-based facilities; including general medicalsurgical floors, intermediate care floors, and emergency departments.

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---- Discussion and Comparison of Predicate and Reference Devices ---

Comment and Comparison	Characteristic	Proposed Device	Predicate Device 510(k) #: 152341	Reference Device 510k#: 150361	Reference Device 510k#: 142827
		hemoglobin (SpO2), pulse rate (PR), skin temperature (TEMP), posture tracking and alarms, and basic arrhythmia (Ventricular Tachycardia, Ventricular Fibrillation, Asystole, Atrial Fibrillation) analysis and alarm in hospital-based facilities including general medical-surgical floors, intermediate care floors, and emergency departments. Continuous non-invasive	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.	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 Monitoring System may be used as standalone devices or networked to a central station through wireless 802.11 communication. Continuous non-invasive blood pressure (cNIBP) measurements have not been evaluated on patients during ambulation. Page 14 The arrhythmia analysis feature is intended for use by healthcare professionals trained in the identification and treatment of arrhythmia events. Automated arrhythmia analysis is an adjunct to clinical assessment; clinician review of the analysis should precede any therapeutic

---- Discussion and Comparison of Predicate and Reference Devices ---

Comment and Comparison	Characteristic	Proposed Device	Predicate Device 510(k) #: 152341	Reference Device 510k#: 150361	Reference Device 510k#: 142827
		blood pressure (cNIBP) measurements have not been evaluated on patients during ambulation. The basic arrhythmia analysis feature is intended for use on patients 18 years of age and older; it has not been evaluated on pediatric patients. The arrhythmia analysis feature is intended for use by healthcare professionals trained in the identification and treatment of arrhythmia	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.		intervention.

---- Discussion and Comparison of Predicate and Reference Devices ---

Comment and Comparison	Characteristic	Proposed Device	Predicate Device 510(k) #: 152341	Reference Device 510k#: 150361	Reference Device 510k#: 142827
		events. Automated arrhythmia analysis is an adjunct to clinical assessment; clinician review of the analysis should precede any therapeutic intervention. 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			

---- Discussion and Comparison of Predicate and Reference Devices ---

Comment and Comparison	Characteristic	Proposed Device	Predicate Device 510(k) #: 152341	Reference Device 510k#: 150361	Reference Device 510k#: 142827
		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.			
Commentary: The Use of Substantial Equivalence, Clinical and Bench Testing and the Use of Consensus Standards	**Substantial Equivalence and the Evolution of Design**	1. Like many other devices the ViSi device has evolved since it was first cleared in 2012. The ViSi Mobile Monitoring system has changed incrementally over time and uses technologies cleared in other devices and is tested against relevant standards as described below. The arrhythmia analysis is based on the same technology as the currently cleared Monebo Technologies, Inc Arrhythmia library (K062282), which has been adapted for real time analysis in the ViSi System. The ViSi Monitoring System arrhythmia analysis has been validated by comparison to the AHA, MIT-BIH, CU, and NST databases as prescribed in ANSI/AAMI EC57: 2012. The safety and effectiveness of the design elements implemented into the ViSi System have been confirmed by compliance to Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm (October 28, 2003).			

---- Discussion and Comparison of Predicate and Reference Devices ---

Comment and Comparison	Characteristic	Proposed Device	**Predicate Device 510(k) #: 152341**	Reference Device 510k#: 150361	Reference Device 510k#: 142827
		The ViSi System has successfully undergone database and 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, and bench testing. The ViSi System has been tested and found to comply with special control guidance and recognized consensus 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. 2. <u>Use of predicate devices.</u> The ViSi system was originally drawn from as many as 14 similar devices as cited in the original 510k #: 112478, cleared on March 22, 2012 The arrhythmia function is reviewed based on customer feedback and was originally cleared in these devices: - Automated ECG Analysis and Interpretation Analysis Software Library (K062282) - Acuity Central Monitoring Station, (K052160) 3. <u>Posture Alarms.</u> Posture related alarms were originally cleared in 510(k) #: 150361. The previously cleared (K143751) ViSi Mobile Monitoring System ("ViSi System") has been modified to include a posture alarms feature set that can alert medical personnel to undesirable patient positions, patient immobility, and patient falls as well display if the patient is walking. The added functionality has been built upon the previously cleared (K143751) system's ability to display whether the patient is upright (stationary), reclined or lying-down.			

---- Discussion and Comparison of Predicate and Reference Devices ---

Comment and Comparison	Characteristic	Proposed Device	**Predicate Device 510(k) #: 152341**	Reference Device 510k#: 150361	Reference Device 510k#: 142827

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. The risk analysis concluded that the benefits in overall patient safety outweighed the risks and therefore the implementation of the additional posture features is worthwhile.

The device design, technology, materials, processes, etc. have not been changed with this application. The modification is only to add the aforementioned posture features; therefore the ViSi Mobile Monitoring System as described in this submission is substantially equivalent to the predicate ViSi System device.

4. Proposed Device- Philosophy of Design and Supporting Changes

The proposed device combines the above technologies and FDA clearances from Sotera into a single device. When combined, this series of changes provides an increased level of patient safety and care and allows health care practitioners to: remotely monitor more than a single patient, configure alarms to broader range to minimize fatigue, allow components to be substituted from other manufactures and communicate across two different ranges of radio frequencies. These incremental changes when combined allow the ViSi system to monitor patients more completely and more robustly while still maintaining its original configuration.

5. The proposed device draws from specific Sotera clearances and has been tested against these standards:
   a. IEC 60601-2-27:2011 Medical Electrical Equipment, Part 2-27: Particular Requirements for The Safety, Including Essential Performance of ECG Monitoring Equipment
   b. AAMI ANSI EC57:2012 Testing and Reporting Performance and Results of Cardiac Rhythm and ST Segment Measurement Algorithms

---- Discussion and Comparison of Predicate and Reference Devices ---

Comment and Comparison	Characteristic	Proposed Device	Predicate Device 510(k) #: 152341	Reference Device 510k#: 150361	Reference Device 510k#: 142827
		c. IEC 60601-2-49:2011 Particular Requirements for The Safety of Multifunction Patient Monitoring Equipment d. IEC 80601-2-30:2009 Medical Electrical Equipment – Part 2-30: Particular Requirements for The Safety, Including Essential Performance, Of Automatic Cycling Non-Invasive Blood Pressure Monitoring Equipment e. ISO 80601-2-61:2011 Particular Requirements for Basic Safety and Essential Performance of Pulse Oximeter Equipment 6. Clinical Testing. Section Twenty of the original submission covers the details surrounding the testing of the ViSi system and in conjunction with cuffs from GE and Welch Allyn Clinical studies have performed to evaluate the accuracy of non-invasive blood pressure (NIBP) measurement according to ISO 80601-2-30. 7. Non-clinical Testing The following bench testing have been performed for substantial comparison: 8. Performance testing 9. Safety testing 10. Risk analysis 11. Software testing			

IV. Table #4. Discussion: 510(k) #: 142827, Arrhythmia and the Proposed Device

a) GENERAL COMPARISON			
Comment and Comparison	**Characteristic**	**Proposed Device ViSi Mobile Monitoring System 510(k) #: K180472**	**ViSi Mobile Monitoring System 510(k) #: K142827**
Same	Manufacturer	Sotera Wireless, Inc.	Sotera Wireless, Inc.
Same	Patient Population	18 years or older	18 years or older
Same	Electrode Configuration	3-wire: II 5-wire: I, II, III, AVL, AVR, AVF, V	3-wire: II 5-wire: I, II, III, AVL, AVR, AVF, V
Same	Common Arrhythmias Detected	Ventricular Tachycardia, Ventricular Fibrillation, Asystole	Ventricular Tachycardia, Ventricular Fibrillation, Asystole
Same	Additional Arrhythmias Detected	Atrial fibrillation and Atrial Flutter	Atrial fibrillation and Atrial Flutter
Same	Environment of Use	Hospital-based facilities; including general medical-surgical floors, intermediate care	Hospital-based facilities; including general medical-surgical floors, intermediate care

a) GENERAL COMPARISON

Comment and Comparison	Characteristic	Proposed Device ViSi Mobile Monitoring System 510(k) #: K180472	ViSi Mobile Monitoring System 510(k) #: K142827
		floors, and emergency departments	floors, and emergency departments
Same	Arrhythmia Analog or Digital	Digital	Digital
Same	Common Mode Rejection Range	> 85 dB	> 85 dB
Different	QRS Detection Sensitivity	AHA: 99.40; MIT 99.50; NST: 95.98 Different	AHA 99.40; MIT 99.46, 79.00
Same	Pacemaker Pulse Rejection	The monitor detects and rejects pacemaker impulses in accordance with IEC 60601-2-27	The monitor detects and rejects pacemaker impulses in accordance with IEC 60601-2-27
Same	Samples Per Second – Bit Resolution	500 samples/sec, 19 bits	500 samples/sec, 19 bits
Same	Alarm Levels/Management Standalone	Vital signs, Arrhythmia	Vital signs, Arrhythmia
Same	Alarm	Vital signs, Arrhythmia	Vital signs, Arrhythmia

a) GENERAL COMPARISON

Comment and Comparison	Characteristic	Proposed Device ViSi Mobile Monitoring System 510(k) #: K180472	ViSi Mobile Monitoring System 510(k) #: K142827
	Levels/Management Connected/Linked		

B) ARRHYTHMIA DETECTION METHOD COMPARISON

Comment and Comparison	Characteristic	Proposed Device ViSi Mobile Monitoring System 510(k) #: K180472	ViSi Mobile Monitoring System 510(k) #: K142827
Enhanced in the Proposed Device Based on Best Available Technology	Asystole	Absence of heat beats for a pre-defined adjustable period between 4 - 15 seconds	Absence of any 'QRS' complexes for at least 4 seconds
	Ventricular Fibrillation	Adaboost multi decision tree classifier and 4 ECG derived features	A rhythm with rapid irregular waves and no distinguishable 'P' waves or 'QRS' complexes
	Ventricular Tachycardia		A sequence of at least 10 consecutive wide 'QRS' complexes (PVCs) at a rate of ≥150 bpm
	Atrial Fibrillation	Two features based on RR interval and higher than user predetermined heart rate (Section)	An irregular rhythm with the absence of "p" waves (Afib) or the dissociation of "p" waves to QRS waves persisting for ≥15 seconds

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B) ARRHYTHMIA DETECTION METHOD COMPARISON

Comment and Comparison	Characteristic	Proposed Device ViSi Mobile Monitoring System 510(k) #: K180472	ViSi Mobile Monitoring System 510(k) #: K142827
	Atrial Flutter	None	
	Artifact / Noisy Signal	None	Spikes, or other 'noise' seen on the ECG trace due to motion, electrical interference, etc. that interfere with heart rate and rhythm analysis for at least 2 seconds.
	Unclassified Rhythm	None	A rhythm or 'QRS' complex that cannot be identified, and is not artifact for at least 2 seconds.

C. Atrial Fibrillation Comparison

S: Subject Device **RA**: Reference Device A ‡: Found in R-00167 (26 Sept 2014)

'–' : null result (test was done, but statistic cannot be calculated due to absence of test or reference annotation)

Database		AF Episode Sensitivity (%)		AF Episode Positive Predictivity (%)		AF Duration Sensitivity (%)		AF duration positive predictivity (%)		AF false positive report		AF False Negative Report		AF time to detection (sec)		Same or Different
		S	RA	S	RA	S	RA	S	RA	S	RA	S	RA	S	RA	
NST		-	-‡	-	0‡	-	-‡	0	0‡	0	1‡	0	0‡	-	-	Same or Better
MIT-BIH	Gross	90	87	100	65	99	80	75	75	0	137	0	10	00:20.94	0:06.4	Same or Better
	Average	92	87	100	37	96	84	71	40							

D. ARRHYTHMIA ALARM COMPARISON

S: Subject Device RA: Reference Device A

Display Message		Alarm Symbol		Basic Arrhythmia Event		Alarm Type		Same or Different
S	RA	S	RA	S	RA	S	RA	
ASYSTOLE	ASYSTOLE			Asystole	Asystole	Life Threatening	Life Threatening	Same
VTACH/VFIB	SUSTAINED V-TACH			Ventricular Tachycardia	Ventricular Tachycardia	Life Threatening	Life Threatening	Same
	VFIB			Ventricular Fibrillation	Ventricular Fibrillation	Life Threatening	Life Threatening	Same
AFIB RVR	AFIB/AFLU			Atrial Fibrillation with specified heart rate above the set limit	Atrial Fibrillation	High Severity	High Severity	Same
AFIB				Atrial Fibrillation with specified heart rate below the set limit	Atrial Fibrillation	General Non-Life Threatening	High Severity	Different

E. ALARM TEST COMPARISON

Units are %

VF – Ventricular Fibrillation

VT – Ventricular Tachycardia

AFIB – Atrial Fibrillation

Call	Database	Subject Device		Reference Device A (K142827)	
		Sensitivity	Positive Predictivity	Sensitivity	Positive Predictivity
VF/VT	AHA	91	100	90	60
	MIT	100	100	100	67
	CU	97	94	94	46
AFIB	MIT	90	100	97	65