510(k) SUMMARY

Stasis Labs, Inc. Stasis Monitoring System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Stasis Labs, Inc.

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Name of Device and Name/Address of Sponsor

Stasis Labs, Inc. Stasis Monitoring System

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10100 Venice Blvd, Ste. 418

Culver City, CA 90232

Common or Usual Name: Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)

Regulation Number: 21 CFR 870.2300

Classification Product Code: MWI

Subsequent Product Codes: DRT, DXN, DQA, FLL

Device Class: Class II

Predicate Device: Sotera Wireless ViSi Mobile Monitoring System (K152341)

Intended Use / Indications for Use:

The Stasis Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult patients (≥21 years of age). It is indicated for 3 lead ECG, respiration rate (RESP), heart rate (HR), noninvasive blood pressure (NIBP), noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (PR), and skin temperature (TEMP) in hospital-based facilities; including, general medical-surgical floors, intermediate care floors, and emergency departments. The Stasis Monitoring System includes bedside patient monitors that communicate with mobile tablets through wireless Bluetooth Low Energy (BLE) communication. The Stasis Monitoring System can generate alerts when rate-based cardiac

arrhythmias such as asystole are detected, and when physiological vital signs fall outside of selected parameters.

The Stasis Monitoring System has a notification system that communicates data and alarms to a Stasis Tablet. It is intended to supplement the primary alarms which originate at the Stasis Monitor device.

Technological Characteristics

The **Stasis Monitoring System** consists of:

- the **Stasis Monitor**
- the **Stasis Tablet**

The **Stasis Monitoring System** consists of a compact six-parameter vital signs monitor that sits at the patient's bedside and communicates via Bluetooth with off the shelf Android tablets running a custom Stasis application. The parameters measured include the following: 3 lead ECG, respiration rate (RESP), heart rate (HR), noninvasive blood pressure (NIBP), noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (PR), and skin temperature (TEMP). The System uses traditional wired sensor technology (i.e., sensors cables are connected to back of Monitor with sensors applied to patient) to acquire the vital signs. All sensors and cables used are off-the-shelf and are already 510(k) cleared as identified in the bulleted list on the following page below. The primary data display and control for the monitoring system is on the Android tablet (see Fig 1 below).

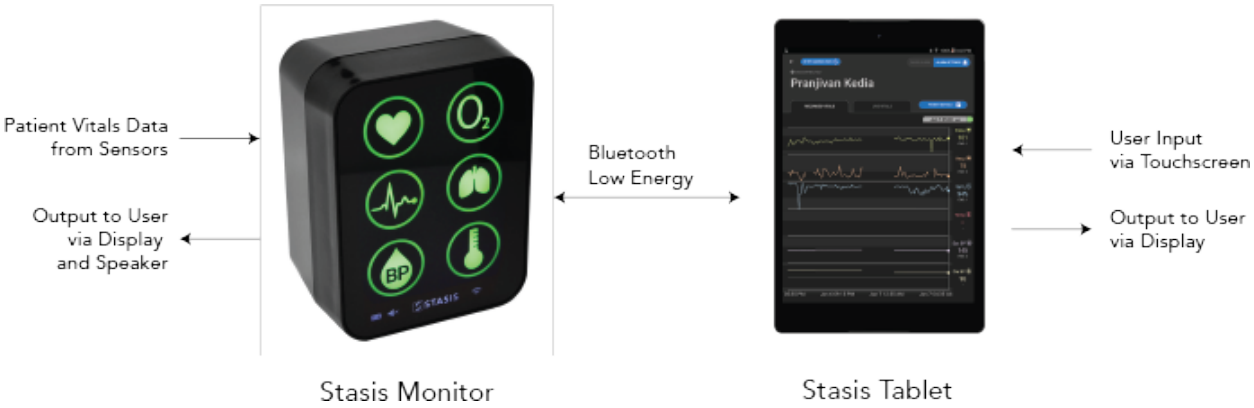

Figure 1—Stasis Monitor and Tablet

The **Stasis Monitor** is mounted near a patient's bed on a custom stand, and sensors collect vital signs data from the patient. The **Stasis Monitor** has a color-coded display to convey vitals sensor and alarm status to clinical staff. It also has a speaker used for audible alarming, a touch sensor on the top to pair a monitor with a Tablet, as well as unique connectors for the various sensor cable connections (see Fig 2 below). The **Stasis Monitor** program interacts with the Stasis Tablet program through wireless communication over Bluetooth Smart (also called Bluetooth Low Energy).

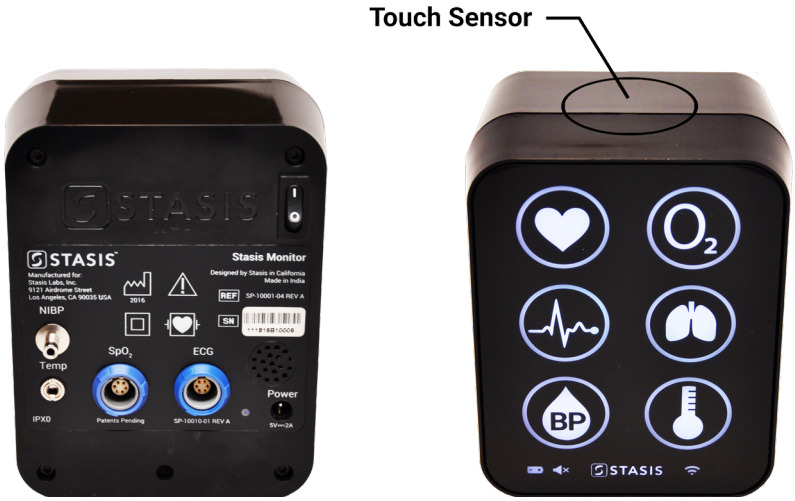

Figure 2—Stasis Monitor (back of Monitor and Touch sensor location)

The **Stasis Tablet** works as a digital patient chart, allowing clinical staff to view patient data, both live vital signs data and recorded vital signs, as well as change settings. It is the primary interface for interacting with the **Stasis Monitoring System**. It also allows clinical staff to set alarm settings on a per-vital sign basis, and view and pause those alarms when they occur. It is the primary interface for interacting with the **Stasis Monitoring System**. The Android tablets running the **Stasis Tablet** application are available off the shelf, but will be provided to users by Stasis Labs with the **Stasis Tablet** application installed.

The **Stasis Monitoring System** requires the following:

- **Stasis Monitor**
  - custom Monitor (containing off-the-shelf batteries for backup power)
  - custom software application that runs Monitor
  - custom Stand (for holding Monitor)
  - off-the-shelf DC power supply (to power Monitor and charge Monitor batteries)
  - off-the shelf sensors/cables that connect to Monitor
    - GE Critikon blood pressure Dura-Cuf cleared by K120125, reusable
    - Edan Instruments blood pressure extension tube cleared by K120144, reusable
    - 3M Red Dot ECG electrode cleared by K970796, single use disposable
    - Unimed Medical Supplies SpO2 sensor and cable cleared by K082546, reusable
    - Unimed Medical Supplies temperature sensor and cable cleared by K121427, reusable
    - Shenzen Med-Link ECG cable cleared by K120010, reusable

- **Stasis Tablet (connected to Monitor via Bluetooth)**
  - Off-the-shelf Android Tablet
  - custom software application that runs Stasis software on Tablet

Pursuant to 807.92(a)(6), basically, both the applicant's device (**Stasis Monitoring System**) and the predicate device (**Sotera Wireless ViSi Mobile Monitoring System**), allow for measurement of 3 lead ECG, respiration rate (RESP), heart rate (HR), noninvasive blood pressure (NIBP), noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (PR), and skin temperature (TEMP) utilizing wireless communication. The only difference in indications for use is the generation of alerts when rate-based cardiac arrhythmias such as asystole are detected, and when physiological vital signs fall outside of selected parameters, which does not constitute a substantive change, as this is simply rate based detection and not specific waveform triggered alerts. The only technological differences between the applicant's device (**Stasis Monitoring System**) and the predicate device (**Sotera Wireless ViSi Mobile Monitoring System**) are the **Stasis Monitoring System** uses Bluetooth communication to Tablet instead of 802.11 wireless communication to a computer, the **Stasis Monitoring System** utilizes off-the-shelf previously 510(k) cleared sensors for vitals monitoring while the predicate measures vitals either at the custom wrist control unit (measuring temperature and NIBP) or with custom sensors that are connected by wires that deploy from the wrist unit to finger (measuring pulse and SpO2) or chest (measuring ECG and respiratory rate) and the **Stasis Monitoring System** displays vitals at the Tablet connected by wireless Bluetooth only while the predicate displays vitals at wrist unit and computer connected by 802.11 wireless communication. Both the applicant's device (**Stasis Monitoring System**) and the predicate device (**Sotera Wireless ViSi Mobile Monitoring System**) have a product code of MWI for Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms), as well as share subsequent product codes of DRT, DXN, DQA and FLL.

The Stasis Monitoring System software is Safety Class C according to ANSI/AAMI/IEC 62304:2006. Determination of the LOC and Safety Class is the result of risk assessment activities per ISO 14971.

STASIS LABS INC.

STASIS MONITORING SYSTEM SUBSTANTIAL EQUIVALENCE CHART

	[Stasis Monitoring System, k183634]	**[Sotera Wireless ViSi Mobile Monitoring System, k152341]**
Indications for Use	The Stasis Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult patients (≥21 years of age). It is indicated for 3 lead ECG, respiration rate (RESP), heart rate (HR), noninvasive blood pressure (NIBP), noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (PR), and skin temperature (TEMP) in hospital-based facilities; including, general medical-surgical floors, intermediate care floors, and emergency departments. The Stasis Monitoring System includes bedside patient monitors that communicate with mobile tablets through wireless Bluetooth Low Energy (BLE) communication. The Stasis Monitoring System can generate alerts when rate-based cardiac arrhythmias such as asystole are detected, and when physiological vital signs fall outside of selected parameters The Stasis Monitoring System has a notification system that communicates data and alarms to a Stasis Tablet. It is intended to supplement the primary alarms which originate at the Stasis Monitor device.	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.
Intended use	Same as above	Same as above
User Population	Healthcare professionals	Healthcare professionals
Classification Product Code	MWI--Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)	MWI--Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)

Subsequent Product Code(s)	DRT, DXN, DQA and FLL	DRT, DXN, DQA, FLL, MSX
Primary component(s)	Software: Custom monitor software, custom tablet application Hardware: Custom monitor (with batteries and power supply), custom monitor stand, off-the-shelf vitals monitoring sensors, off-the-shelf tablet	Software: Custom monitor software, custom computer software Hardware: Custom wrist monitor, custom finger and chest sensors, off-the-shelf computer
Wireless communication	Bluetooth	802.11 (Wifi)
Safety Features	Risk analysis developed in accordance with ISO 14971	Not available in 510(k), assumed in accordance with ISO 14971
Software level of concern	Major level of concern	Not available in 510(k), assumed to be major per IEC 62304:2006
Standards used and testing performed	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-8, IEC 60601-2-27, IEC 60601-2-49, IEC 80601-2-30, IEC 80601-2-61, IEC 80601-2-56, IEC 62304, ANSI C63.27 (2017)	Not available in 510(k)
Respiratory rate (RR) operating principle	Impedance Pneumography measuring in respirations per minute (or RPM)	Impedance Pneumography in breaths per minute (same as RPM)
Default RR Alarms Settings	10 RPM lower, 25 RPM higher	4 RPM lower, 35-40 RPM higher
RR Alarms Settings Tunable for User?	Yes	Yes
RR Min/Max Alarm settings	6 RPM lower, 50 RPM higher	Not specified
RR Display Range	0-50 RPM	0-50 RPM
RR Accuracy Range	7-45 RPM	3-50 RPM
RR Resolution	1 RPM	1 RPM
RR Accuracy	±3 RPM	± 3 BR/MIN or 10% of reading, whichever is greater
Respiration Drive Signal Applied to Patient	Voltage: 0.8 V P-P Frequency: 32.5 KHz	Voltage: 1.0 V P-P ± 5% Frequency: 32 KHz ± 2%

Electrical Testing

EMC testing per IEC 60601-1-2 and leakage current testing per IEC 60601-1-1 were performed for the **Stasis Monitoring System**. All test results were acceptable for the **Stasis Monitoring System**.

Coexistence Testing

Pursuant to 807.92(b)(1), coexistence testing was performed on the **Stasis Monitoring System** per ANSI C63.27 (2017) using the radiated open environment (ROE) method. The **Stasis Monitoring System** was tested as Tier 1 device per ANSI C63.27 (2017). The **Stasis Monitoring System** passed testing and pursuant to 807.92(b)(3), the results of coexistence testing demonstrate that the **Stasis Monitoring System** is as safe and effective as the predicate devices and is substantially equivalent to the legally marketed predicate device **Sotera Wireless ViSi Mobile Monitoring System** per k152341, and that **Stasis Monitoring System** performs as well as legally marketed predicate device **Sotera Wireless ViSi Mobile Monitoring System per** k152341.

Performance Data

Pursuant to 807.92(b)(1), testing for **Stasis Monitoring System** was performed to ensure that all functional requirements have been met, and that core functions execute as expected. Testing was conducted in-house by trained personnel using simulators to obtain the functional and accuracy test results. Testing was also conducted by 3rd party trained personnel using simulators to obtain the functional and accuracy test results. Verification testing was performed on code and the tests performed passed with all required results. Validation testing was performed on software, which confirmed that software met all requirements and operated as intended. All test steps from the validation protocol passed.

Pursuant to 807.92(b)(3), the results of these performance tests demonstrate that the **Stasis Monitoring System** validation and non-clinical testing (electrical testing, coexistence testing) is within specification. As such, pursuant to 807.92(b)(3) the **Stasis Monitoring System** is as safe and effective as the predicate devices and is substantially equivalent to **Sotera Wireless ViSi Mobile Monitoring System** per k152341. The software performs as well as legally marketed predicate device **Sotera Wireless ViSi Mobile Monitoring System** per k152341.

Stasis Monitoring System indications for use are drawn from the indications for use of a legally marketed predicate device: **Sotera Wireless ViSi Mobile Monitoring System**. **Stasis Monitoring System** draws from features of this predicate device and does not provide novel functionality. As such, the features provided by **Stasis Monitoring System** do not in themselves raise new concerns of safety or effectiveness.

In all instances, the **Stasis Monitoring System** functioned as intended and the operation observed was as expected.

Substantial Equivalence

The **Stasis Monitoring System** is as safe and effective as the **Sotera Wireless ViSi Mobile Monitoring System**. The **Stasis Monitoring System** has similar intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. A minor difference in indications for use is the generation of alerts when rate-based cardiac arrhythmias such as asystole are detected, and when physiological vital signs fall outside of selected parameters, which

does not constitute a substantive change, as this is simply rate based detection and not specific waveform triggered alerts. The minor technological differences between the **Stasis Monitoring System** and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the **Stasis Monitoring System** is as safe and effective as the **Sotera Wireless ViSi Mobile Monitoring System**. Thus, the **Stasis Monitoring System** is substantially equivalent.