DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 4, 2016

Mortara Instrument, Inc.
Sarah Weber
Senior Regulatory Affairs Manager
7865 North 86th Street
Milwaukee, Wisconsin 53224

Re: K160685
Trade/Device Name: Surveyor S4 Mobile Monitor
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, DQA, DPS
Dated: June 28, 2016
Received: June 29, 2016

Dear Sarah Weber:

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,

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

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 below.

510(k) Number *(if known)*
K160685

Device Name
Surveyor S4 Mobile Monitor

Indications for Use *(Describe)*

The Surveyor S4 Mobile Monitor is indicated for use:

• The Surveyor S4 is indicated for use to acquire, analyze and output multi-lead ECG and SpO2 signals. The Mortara Surveyor S4 mobile monitor facilitates the monitoring of ECG and SpO2 parameters when used in conjunction with alarm annunciating devices such as the Surveyor Central Station for telemetric monitoring; however, the Surveyor S4 has no alarming capabilities of its own.

- The Surveyor S4 processes Heart rate, ST segment deviation and arrhythmias such as, but not limited to, Ventricular Tachycardia, Ventricular Fibrillation, and Asystole by utilizing Mortara VERITAS™ ECG algorithm

• The Surveyor S4 can deliver data from a 3/5 lead cable and diagnostic 12-lead ECG data to a receiving Surveyor Central station.
• The Surveyor S4 mobile monitor is indicated for use as a mobile radio transceiver, allowing the patient to be ambulatory within the range of a Wi-Fi information infrastructure.
• The Surveyor S4 mobile monitor is indicated for use in adults, adolescents and children.
• The Surveyor S4 mobile monitor is a prescription device intended to be used by knowledgeable healthcare professionals within a healthcare or clinical setting. It is not intended as a sole means of diagnosis.

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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Traditional 510(k) Notification

Section 5

510(k) Summary Statement

1. Submitter

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2. Product Names

Device Trade Name	Surveyor S4 Mobile Monitor
Common/ Usual Name	Monitor, Physiological, Patient (With Arrhythmia Detection or Alarms) Oximeter Electrocardiograph
Classification	Monitor, Physiological, Patient (With Arrhythmia Detection or Alarms) 870.1025 MHX Oximeter 870.2700 DQA Electrocardiograph 870.2340 DPS

Traditional 510(k) Notification

Note: There are no previous submissions for this device

3. Predicate Device to which this is Substantially Equivalent

Surveyor S4 Mobile Monitor	K141020
ApexPro Telemetry System	K080251

The primary predicate device is Surveyor S4 Mobile Monitor, K141020.

The S4 predicate device has not been subject to a design-related recall. The ApexPro predicate device does has not been under recall since 2011, Z-1522-2011.

4. Device Description

The Surveyor™ S4 Mobile Monitor is a battery operated patient worn transceiver that communicates via IEEE 802.11 Wi-Fi technology to the Surveyor™ Central Station (K131929) which is the primary monitoring display and alarm source.

The Surveyor S4 transmitter has a touch sensitive, color display allowing for operational conveniences such as a battery level indicator, Wi-Fi Signal Strength and Surveyor Central Station slot information. The Surveyor S4 can display physiological waveforms, measured parameters, demographic data and other status information. The Surveyor S4 acquires, filters, and processes ECG or ECG and SpO2 parameters and sends filtered signals and parameters to the Surveyor Central Station where alarm processing and annunciation occurs.

The Surveyor Central is designed to communicate with the Surveyor S4 within a healthcare facilities Wi-Fi network infrastructure. The Surveyor Central provides primary monitoring of telemetry patients when used with the Surveyor S4. The central station displays numeric values, waveforms, alarm generation and management, data storage, individualized patient management, report generation and printing functionality.

The Surveyor S4 provides continuous data acquisition which can be visualized on the S4 itself for the following parameters:

- Electrocardiography (ECG) including heart rate and ECG waveforms
- Saturation percentage of peripheral oxygen (SpO2), including SpO2 plethysmogram waveform, pulse rate, and signal quality index.
- No alarm status or processing information of ECG or SpO2 is shown on the Surveyor S4 device.

ECG

- The Surveyor S4 processes Heart rate, ST segment deviation and arrhythmias, by utilizing Mortara VERITAS™ ECG algorithm and sends ECG data packets, including arrhythmias such as, but not limited to, Ventricular Tachycardia, Ventricular Fibrillation, and Asystole to the Surveyor Central Station for alarm processing and annunciation.
- The Surveyor S4 utilizes proprietary ECG lead cables available in AHA or IEC, snap or clip, 3-Lead, 5-Lead, and diagnostic 12 Lead configurations.

SpO2

- The Surveyor S4 processes SpO2 percentage, pulse rate and signal quality through the Mortara SpO2 algorithm and sends data packets for SpO2 to the Surveyor Central Station for alarm processing and annunciation.
- Multiple SpO2 sensor styles allow connection of adults, adolescents, and children. SpO2 sensors are specified for use with the Surveyor S4 and available through Mortara Instrument.

5. **Intended Use**

The Surveyor S4 Mobile Monitor is indicated for use:

•The Surveyor S4 Mobile Monitor is indicated for use to acquire, analyze and output multi-lead ECG and SpO2 signals.

The Mortara Surveyor S4 mobile monitor facilitates the monitoring of ECG and SpO2 parameters when used in conjunction with alarm annunciating devices such as the Surveyor Central Station for telemetric monitoring; however, the Surveyor S4 has no alarming capabilities of its own.

• The Surveyor S4 processes Heart Rate, ST segment deviation and arrhythmias such as, but not limited to, Ventricular Tachycardia, Ventricular Fibrillation, and Asystole by utilizing Mortara VERITAS™ ECG algorithm.

• The Surveyor S4 can deliver data from a 3/5-lead cable and diagnostic 12-lead ECG data to a receiving Surveyor Central station

• The Surveyor S4 Mobile Monitor is indicated for use as a mobile radio transceiver, allowing the patient to be ambulatory within the range of a Wi-Fi information infrastructure.

• The Surveyor S4 Mobile Monitor is indicated for use in adults, adolescents and children.
• The Surveyor S4 Mobile Monitor is a prescription device intended to be used by knowledgeable healthcare professionals within a healthcare or clinical setting. It is not intended as a sole means of diagnosis.

6. **Technological Characteristics**

The Surveyor S4 Mobile Monitor employs the same functional scientific technology as its predicate device Surveyor S4 Mobile Monitor (K141020). It is a prescription device designed to acquire and transmit diagnostic quality ECG in a clinical setting while allowing the patient to be ambulatory. The Surveyor S4 Mobile Monitor is suitable for use as a telemetry solution within centralized ECG monitoring systems or other clinical settings for patients connected to telemetry transceivers

The Surveyor S4 Mobile Monitor is designed to work with ECG when used with a compatible multi-parameter Telemetry Central Station System such as the Mortara Surveyor Central Station (K131929) and other compatible receiving devices.

The Surveyor S4 Mobile Monitor was designed and manufactured by Mortara Instrument according to 21 CFR Part 820. The Surveyor S4 Mobile Monitor is substantially equivalent to The Surveyor S4 Mobile Monitor (Predicate K141020) with the following technological differences:

- Added 3/4/5 lead ECG
- Added shielded 3/4/5- wire ECG patient cable
- Added SpO_2 functionality
- Added SpO_2 sensor with optional extender cable

Comparison Matrix:

510(k)	K080251	K141020	Present Submission	**Change explanation**
BRAND	ApexPro	Surveyor S4 Mobile Monitor (Primary)	Surveyor S4 Mobile Monitor	
COMPANY	GE Medical Systems Information Technologies	Mortara Instrument, Inc.	Mortara Instrument, Inc.	
Software Version	Proprietary	V1.00	V1.2.0	
510 (K) Number	K080251	K141020	Present Application	
Indications for Use	The ApexPro Telemetry System is	The Surveyor S4 Mobile Monitor is indicated for use:	The Surveyor S4 Mobile Monitor is indicated for use: • The Surveyor S4	Equivalent. Indications revised

510(k)	K080251	K141020	Present Submission	Change explanation
BRAND	ApexPro	Surveyor S4 Mobile Monitor (Primary)	Surveyor S4 Mobile Monitor	
COMPANY	GE Medical Systems Information Technologies	Mortara Instrument, Inc.	Mortara Instrument, Inc.	
Software Version	Proprietary	V1.00	V1.2.0	
510 (K) Number	K080251	K141020	Present Application	
	intended for use under the direct supervision of a licensed healthcare practitioner. The system is designed to acquire and monitor physiological data for ambulating patients within a defined coverage area. The system processes this physiological data to detect various ECG arrhythmia events and select physiological parameter limit violations. The ApexPro Telemetry System is intended to be installed in the hospital or clinical environment in order to provide clinicians with patient physiological data, while allowing for patient mobility. These systems are	• The Surveyor S4 Mobile Monitor is indicated for use in adult & pediatric patient populations. The Mortara Surveyor S4 Mobile Monitor facilitates the monitoring of ECG signals. • The Surveyor S4 Mobile Monitor is a prescription device intended to be used by knowledgeable healthcare professionals within a healthcare facility or clinical pharmacology unit. • The Surveyor S4 Mobile Monitor is indicated for use in a clinical setting by a physician, or by trained personnel acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis. • The Surveyor S4 Mobile Monitor is indicated for use to acquire and output electrocardiographic data. • The Surveyor S4 Mobile Monitor is indicated for use as a	Mobile Monitor is indicated for use to acquire, analyze and output multi-lead ECG, SpO_2 and other physiological signals. The Mortara Surveyor S4 Mobile Monitor facilitates the real-time monitoring of clinical parameters when used in conjunction with alarm annunciating devices such as a Central Station for telemetric monitoring. • The Surveyor S4 can deliver diagnostic 12-lead ECG data to a receiving station. • The Surveyor S4 Mobile Monitor is indicated for use as a mobile radio transceiver, allowing the patient to be ambulatory within the range of a Wi-Fi information infrastructure. • The Surveyor S4 Mobile Monitor is indicated for use in adults, adolescents and children. • The Surveyor S4 Mobile Monitor is a prescription device intended to	for clarity and to provide patient population categories in accordance with FDA guidance "*Providing Information about Pediatric Uses of Medical Devices - Guidance for Industry and Food and Drug Administration Staff***"** dated May 1, 2014. Added SpO_2 functionality.

510(k)	K080251	K141020	Present Submission	**Change explanation**
BRAND	ApexPro	Surveyor S4 Mobile Monitor (Primary)	Surveyor S4 Mobile Monitor	
COMPANY	GE Medical Systems Information Technologies	Mortara Instrument, Inc.	Mortara Instrument, Inc.	
Software Version	Proprietary	V1.00	V1.2.0	
510 (K) Number	K080251	K141020	Present Application	
	typically deployed in sub-acute care areas in hospitals or clinical sites where patient mobility can enhance the effectiveness of the medical procedures administered. The physiological parameters monitored include ECG, noninvasive blood pressure, non-invasive temperature and SpO2. The ApexPro Telemetry System is intended to provide ECG data via Ethernet to the computer platform for processing. The ApexPro Telemetry System is also intended to provide physiologic data over the Unity Network to clinical information systems for display.	radiofrequency physiological signal transceiver, receiving and delivering real-time acquisition and transmission of simultaneous electrocardiographic data, while allowing the patient to be ambulatory within the range of the antenna network. The Mortara Li-Ion Battery Charger is intended for charging only the Mortara Rechargeable Li-Ion battery pack.	be used by knowledgeable healthcare professionals within a healthcare or clinical setting. It is not intended as a sole means of diagnosis.	

510(k)	K080251	K141020	Present Submission	**Change explanation**
BRAND	ApexPro	Surveyor S4 Mobile Monitor (Primary)	Surveyor S4 Mobile Monitor	
COMPANY	GE Medical Systems Information Technologies	Mortara Instrument, Inc.	Mortara Instrument, Inc.	
Software Version	Proprietary	V1.00	V1.2.0	
510 (K) Number	K080251	K141020	Present Application	
Operating System	Proprietary	Linux derivative	Linux derivative	Equivalent
Network Interface	Digital/608-614 Mhz	Digital/Wireless network interface per IEEE 802.11g/n	Digital/Wireless network interface per IEEE 802.11g/n	Equivalent Both devices use a digital, wireless form of communication but utilize different frequency ranges and signaling protocol.
Target Population	Adult, pediatric	Adult, pediatric	Adults, adolescents, children	Equivalent. Subject device includes a subset of the Adults to Neonate population of the predicate device. Revised patient population categories in accordance with FDA guidance "*Providing Information about Pediatric Uses of Medical Devices - Guidance for Industry and Food and Drug Administration Staff***"** dated May 1, 2014.
ECG	3, 5, or 6-lead ECG	12-lead diagnostic ECG	3/4/5-lead, and12-lead diagnostic ECG	Equivalent

510(k)	K080251	K141020	Present Submission	**Change explanation**
BRAND	ApexPro	Surveyor S4 Mobile Monitor (Primary)	Surveyor S4 Mobile Monitor	
COMPANY	GE Medical Systems Information Technologies	Mortara Instrument, Inc.	Mortara Instrument, Inc.	
Software Version	Proprietary	V1.00	V1.2.0	
510 (K) Number	K080251	K141020	Present Application	
ECG Sampling Rate	240 samples/second	500 Samples/second	500 samples/sec	Equivalent The subject device is equivalent to the previous submission of the same device.
SpO_2	Yes	No	Yes	New functionality added
Graphic Display	No	Yes	Yes	Equivalent
Frequency Transmission	608-614 WMTS or 1,395-1,400 WMTS, dependent on transmitter model	IEEE 802.11g/n, 2.4 GHz band	IEEE 802.11g/n, 2.4 GHz band	Equivalent
Transmission Type	Channelized	Digital wireless in accordance with IEEE 802.11g/n	Digital wireless in accordance with IEEE 802.11g/n	Equivalent
Battery Type	2 AA	3 AA disposable, or rechargeable Li-Ion Pack	3 AA disposable, or rechargeable Li-Ion Pack	Equivalent
Lead Check	Yes	Yes	Yes	Equivalent
Internal Antenna	No	Yes	Yes	Equivalent
Compatible Systems	CARESCAPE Central Station (K133882)	Surveyor Central Station (K131929)	Surveyor Central Station (K131929)	Equivalent
Patient Cable	3, 5, and 6-wire Multi-Link Leadwires	LeadForm 10-wire ECG	LeadForm 10-wire ECG Shielded 3/4/5-wire ECG	Equivalent

510(k)	K080251	K141020	Present Submission	**Change explanation**
BRAND	ApexPro	Surveyor S4 Mobile Monitor (Primary)	Surveyor S4 Mobile Monitor	
COMPANY	GE Medical Systems Information Technologies	Mortara Instrument, Inc.	Mortara Instrument, Inc.	
Software Version	Proprietary	V1.00	V1.2.0	
510 (K) Number	K080251	K141020	Present Application	
SpO_2 Cable	Masimo uSpO2 pulse oximetry utilizing Masimo SET Measure-through Motion and low perfusion pulse oximetry technology with compatible LNCS style sensors.	N/A	SpO_2 sensors – disposable, clip, SoftTip™ w/ optional extender cable	Equivalent Added SpO_2 as a new feature to subject device.

7. Determination of Substantial Equivalence – Non-clinical

Software verification and validation testing was conducted as recommended by FDA's Guidance for Industry and FDA Staff, *"Guidance for the Content fo Premarket Submissions for Software Contained in Medical Devices"* and *"Off-the-Shelf Software Use in Medical Devices."*

The Surveyor S4 Mobile Monitor was designed and tested for compliance with the applicable clauses of the following standards:

Traditional 510(k) Notification

- IEC 60601-1:2005 Ed:3 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-49: 2011 Medical electrical equipment Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
- IEC 60601-1-2:2007 Medical Electrical Equipment – Part 1-2: General requirements for safety and essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and tests

- ISO 80601-2-61:2011 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- IEC 60601-2-25:2011-10 Edition 2.0, Medical Electrical Equipment. Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
- ANSI/AAMI EC57:2012 Testing and reporting performance results of cardiac rhythm, ST segment measurement algorithms, ventricular fibrillation algorithm, and irregular rhythm (atrial fibrillation) algorithm

8. **Determination of Substantial Equivalence – Clinical**

A basic pulse oximeter clinical study was conducted to demonstrate the Surveyor S4 Mobile Monitor SpO2 compliance to IEC 80601-2-61. The study met the requirements of ISO 80601-2-61-2011 Clause 201.12.1.

9. Conclusion

Changes to the Surveyor S4 Mobile Monitor include:

- Added SpO2 functionality
- Added SpO2 extender cable
- Added shielded 3/4/5-wire ECG

Mortara Instrument, Inc. considers the Surveyor S4 Mobile Monitor to be as safe, as effective and performance is substantially equivalent to the predicate devices.