January 24, 2019

Mortara Instrument, Inc.
Marco Manduchi
QA/RA Manager
7865 North 86th Street
Milwaukee, Wisconsin 53224

Re: K182297
Trade/Device Name: Surveyor S2
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG
Dated: December 20, 2018
Received: December 26, 2018

Dear Marco Manduchi:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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,

Jessica E. Paulsen -S

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)*
K182297

Device Name
Surveyor S2

Indications for Use *(Describe)*
The Surveyor S2 is indicated for use:
• The Surveyor S2 is indicated for use in adult, adolescents, and children patient populations. The Surveyor S2 facilitates the monitoring of ECG signals.
• The Surveyor S2 is a prescription device intended to be used by knowledgeable healthcare professionals within a healthcare facility or clinical pharmacology unit.
• The Surveyor S2 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 S2 is indicated for use to acquire and output electrocardiographic data.
• The Surveyor S2 is indicated for use as a 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.

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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510(k) Summary

[As described in 21 CFR 807.92]

Submitted by:	Mortara Instrument, Inc. 7865 North 86th Street Milwaukee, WI 53224 U.S.A.
Contact Person Primary Contact:	Marco Manduchi Regulatory Affairs Manager Phone: +39 - 0512987821 marco.manduchi@welchallyn.com
Secondary Contact:	Mark Elliott VP Global RA/QA Phone: 414-354-1600 Mark.Elliott@Mortara.com
Date Prepared:	July 31, 2018
Trade Name:	Surveyor S2
Common Name	Transmitters and receivers, physiological signal, radiofrequency
Classification Reference:	Class II, Transmitters and receivers, physiological signal, radiofrequency (21 CFR 870.2910, Product code DRG)
Predicate device:	Surveyor S4 Mobile Monitor 510(k) Number: K141020 Transmitters and receivers, physiological signal, radiofrequency, 21 CFR 870.2910 Class II, DRG

Device Description

The Surveyor S2 is a patient-worn, battery-powered telemetry transmitter. The Surveyor S2 is intended to acquire ECG signals and transmits waveforms and corresponding status to a receiving S2 Communication Library. The S2 Communication Library, to be integrated in an external monitoring node for processing, exposes an API to obtain ECG signals and push session status, parameters and demographic information to the S2.

The ECG acquired signals are transmitted through the S2 communication Library to the Monitoring Node for further processing, presentation, storage, etc via the hospital/clinic wireless and wired network infrastructure. The Surveyor S2 is designed to be used within the existing network IT infrastructure.

The Surveyor S2 has a 2.8'' color display with a capacitive touch sensitive screen, allowing for operational conveniences such as a battery level indicator, Wi-Fi Signal Strength and on-demand visual indication of the status of its connection to the monitoring node. The Surveyor S2 acquires and sends signals to the monitoring node where ECG signal processing and monitoring occurs. The Surveyor S2 displays ECG derived parameters (Heart Rate) and demographic data and monitoring state as received from the monitoring node through the S2 Communication Library.

The Surveyor S2 provides continuous data acquisition which can be visualized on the S2 itself for the ECG waveforms.

The Surveyor S2 utilizes ECG lead cables available in AHA or IEC, snap or clip, 4-wire Lead. ECG data delivered is 3-leads, lossless compressed, 2.5 µV LSB at 500 samples per second.

ECG data is augmented with electrode fail markers, lead identifications, hardware detected pacemaker spikes.

Indication for use

The Surveyor S2 is indicated for use:

- The Surveyor S2 is indicated for use in adult, adolescents, and children patient populations. The Surveyor S2 facilitates the monitoring of ECG signals.
- The Surveyor S2 is a prescription device intended to be used by knowledgeable healthcare professionals within a healthcare facility or clinical pharmacology unit.

- The Surveyor S2 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 S2 is indicated for use to acquire and output electrocardiographic data.
- The Surveyor S2 is indicated for use as a 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.

Technological Characteristics

The Surveyor S2 employs the same functional scientific technology as its predicate device Surveyor S4 (K141020). It is a prescription device designed to acquire and transmit ECG in a clinical setting while allowing the patient to be ambulatory. The Surveyor S2 is suitable for use as a telemetry solution within centralized ECG monitoring node systems or other clinical settings for patients connected to telemetry transceivers.

The Surveyor S2 is designed and manufactured by Mortara Instrument according to 21 CFR Part 820. Surveyor S2 is substantially equivalent to Surveyor S4 (Predicate K141020) with the following technological differences:

- Surveyor S2 is designed to communicate with a S2 communication Library a C++ software library intended to provide a consistent, tested and reusable interface for integrating the S2 Wi-Fi telemetry transmitter into a monitoring node.
- S2 and S4 has a different WLAN module, but both use a Wi-Fi network interface. Surveyor S4 supports only IEEE 802.11 b/g/n at 2.4 GHz band whereas S2 supports IEEE 802.11 a/b/g/n on 2.4GHz and 5GHz band.
- Surveyor S2 supports 4-wire lead

Moreover, modifications were made to the Surveyor S2 to provide the same functionality of the predicate device Surveyor S4 in a smaller size, to reduce the weight of the device, to improve the battery duration and to improve the touch screen responsiveness.

Device Comparison Table:

Predicate Device and Subject Device Comparison			
Characteristic	**Predicate device**	**Subject device**	**Change explanation**
Device	Surveyor S4	Surveyor S2	Model Number
COMPANY	Mortara Instrument, Inc.	Mortara Instrument, Inc.	Same
510(k) number	K141020	N/A	N/A
Software Version	V1.00	V1.0.0	Since the device has a different model number has been created a new software version.
Product Code	DRG	DRG	Same
Classification Name	Class II Transmitters and receivers, physiological signal, radiofrequency	Class II Transmitters and receivers, physiological signal, radiofrequency	Same
Regulation Number	21 CFR 870.2910	21 CFR 870.2910	Same
Intended use	The Surveyor S4 is indicated for use: The Surveyor S4 is indicated for use in adult & pediatric patient populations. The Surveyor S4 facilitates the monitoring of ECG signals. The Surveyor S4 is a prescription device intended to be used by knowledgeable healthcare professionals within a healthcare facility or clinical pharmacology unit. The Surveyor S4 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 is indicated for use to acquire and output electrocardiographic data. The Surveyor S4 is indicated for use as a	The Surveyor S2 is indicated for use: The Surveyor S2 is indicated for use in adult, adolescents, and children patient populations. The Surveyor S2 facilitates the monitoring of ECG signals. The Surveyor S2 is a prescription device intended to be used by knowledgeable healthcare professionals within a healthcare facility or clinical pharmacology unit. The Surveyor S2 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 S2 is indicated for use to acquire and output electrocardiographic data. The Surveyor S2 is indicated for use as a radiofrequency physiological	Same Surveyor S2 indications for use have been revised for clarity 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. Surveyor S2 is not provided with a specific Mortara li-on battery Charger. Surveyor S2 use a OEM battery recharger. The new battery charger has been tested for safety by the supplier and to demonstrate proper charging across each charging port as well as demonstrating proper LED functions for the charger.

Predicate Device and Subject Device Comparison			
Characteristic	**Predicate device**	**Subject device**	**Change explanation**
	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.	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.	
Standard Compliance	IEC 60601-1:2005 IEC 60601-1-2:2007 IEC 60601-2-27:2011 IEC 60601-1-6:2010 IEC 62366:2007-10 ISO10993-1:2009 ISO10993-5: 2009 ISO10993-10: 2010 EN 62304:2006 ISO 14971:2007	IEC 60601-1:2005 Ed 3.1 IEC 60601-1-2:2014 Ed 4.0 IEC 60601-2-27:2011 Ed 3.0 IEC 60601-1-6:2010 Ed 3.1 IEC 62366:2014 Ed.1.1 ISO 10993-1:2009 Ed 4 ISO 10993-5:2009 Ed 3 ISO 10993-10:2010 Ed 3 IEC 62304:2006 Ed 1, ISO 14971:2007 Ed 2.	Equivalent, Surveyor S2 has been designed in conformity with the same standard of the predicate Surveyor S4. Surveyor S2 follow the new version of the IEC 60601-1-2.
Network Interface and Frequency Transmission	Digital/Wireless network interface per IEEE 802.11 b/g/n 2.4 GHz band	Digital/Wireless network interface per IEEE 802.11a/g/n, 2.4 or 5GHz bands	S2 use the same network interface of S4. S2 differently from S4 use also 5Ghz Frequency Transmission. This new feature has been tested in the V&V documentation.

Predicate Device and Subject Device Comparison			
Characteristic	**Predicate device**	**Subject device**	**Change explanation**
Target Population	Adults, pediatrics	Adults, adolescents, children	Equivalent. Subject device includes a subset of the Adults to Children 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.
Where used	Health care facilities	Health care facilities	Same
ECG	12-lead diagnostic ECG	3-lead ECG	Equivalent, S2 uses the a 3-lead ECG, this function has been cleared in the K160685. Moreover, Surveyor S2 functionality with 3-lead ECG has been tested in the system V&V.
Patient Cable	LeadForm 10-wire ECG	Shielded 4-wire ECG	Equivalent, S2 uses the a 4-wire ECG cable, this cable has been cleared in the K160685. Moreover, Surveyor S2 functionality with 4-wires ECG cable has been tested in the system V&V.
ECG Sampling Rate	500 Samples/sec	500 samples/sec	Same
Graphic Display	Yes	Yes	Equivalent
Touch screen	Resistive Touch screen	Capacitive touch screen	Equivalent, this modification improves the responsiveness of the device, and allow the Surveyor S2 do not be calibrated. Capacitive touch screen responsiveness has been tested in the hardware verification.
Display Size	4''	2,8''	Equivalent, this modification reduces the dimension of the device.

Predicate Device and Subject Device Comparison			
Characteristic	**Predicate device**	**Subject device**	**Change explanation**
Battery Type	3 AA disposable, or rechargeable Li-Ion Pack	Rechargeable Li-Ion Pack	S2 is not powered by AA disposable battery, but only by a rechargeable Li-ion Pack. S2 rechargeable Li-ion Pack is equivalent to S4.
Rechargeable Battery Run-Time	24 hrs	32 Hrs	Similar. This new feature has been tested.
Signal Processing	Signal fail detection and waveform filtering for local display	Signal fail detection and waveform filtering for local display	Same
Lead Check	Yes	Yes	Same
Internal Antenna	Yes	Yes	Same
Dimension	5.5” x 3.1” x 1.3” (139 x 79 x 33 mm)	3.5” x 2.8” x 1.1” (89 × 71 × 28 mm)	Surveyor S2 provide the same functionality of the predicate device Surveyor S4 in a smaller size.
Weight	300g with battery.	200g with battery	Surveyor S2 provide the same functionality of the predicate device Surveyor S4 with a minor weight.

Non-clinical Test

The Surveyor S2 was tested based on the following standards:

- IEC 60601-1:2005 Ed:3.1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Ed.4.0 Medical Electrical Equipment – Part 1-2: General requirements for safety and essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and tests
- IEC 60601-2-27:2011 Ed.3.0/Cor.1:2012, Medical Electrical Equipment – Part 2 27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
- ISO 10993-1:2009/Cor.1:2010, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- AAMI/ANSI/ISO 10993-5:2009/(R)2014, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10:2010, Biological evaluation of medical devices – Part 10:

Tests for irritation and skin sensitization

- IEC 60601-1-6:2010+A1:2013‑Ed.3.1, Medical electrical equipment – Part 1- 6: General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 62366:2014-Ed.1.1, Medical devices – Application of usability engineering to medical devices
- IEC 62304:2006 Ed. 1, medical device software - software life cycle processes.
- ISO 14971:2007 Ed 2 medical devices - application of risk management to medical devices.

Performance testing for the Surveyor S2 includes software verification and validation test, software unit test, integration test, system test and testing to compliance standards for electrical and electromagnetic safety. Wireless coexistence testing and evaluation was performed following FDA Guidance, “Radio Frequency Wireless Technology in Medical Device”, and the device’s immunity to proximity fields from radio frequency wireless communications equipment was validated. Traceability has been documented between all specifications to verification and validation test results.

Clinical Performance Data

No clinical studies were utilized for the purpose of obtaining data.

Conclusion

Based on the information presented in this 510(k) premarket notification, the Surveyor S2 is considered substantially equivalent to devices in commercial distribution and its predicate devices Surveyor S4 (K141020).

The differences noted between the Surveyor S2 and the predicate device do not impact the device based on the successfully conducted testing of the device.