DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 11, 2017

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

Re: K161517
Trade/Device Name: Surveyor S12 and S19 Patient 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, MLD, DSJ, DSB, MSX, DSI
Dated: September 27, 2016
Received: September 28, 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.

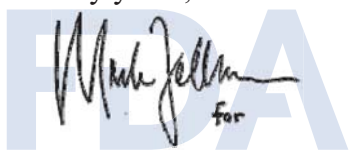
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

Enclosure

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)*

K161517

Device Name
Surveyor S12 and S19 Patient Monitor

Indications for Use *(Describe)*

The Mortara Surveyor Patient Monitor is indicated for use in adult, adolescents, and children patient populations for the monitoring of the following paramaters:

- Non-invasive blood pressure
- Impedance respiration
- Invasive blood pressure
- Temperature
- Functional arterial oxygen saturation (SpO2)
- End-tidal & inspired CO2
- ECG monitoring with arrhythmia & ST-segment
- 12-Lead resting ECG
- Cardiac output

The Mortara Surveyor Patient Monitor is indicated for use in infants and neonatal patient populations for the monitoring of the following parameters:

- Non-invasive blood pressure
- Impedance respiration
- Invasive blood pressure
- Temperature
- Functional arterial oxygen saturation (SpO_2)
- End-tidal & inspired CO_2
- ECG monitoring with arrhythmia
- 12-Lead resting ECG

The Mortara Surveyor Patient Monitor is a prescription device intended to be used by healthcare professionals in all areas of a healthcare facility.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff

Section 5

510(k) Summary Statement

1. Submitter

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Primary Contact

Sarah Weber
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2. Product Names

Device Trade Name	Surveyor S12 and S19 Patient Monitor
Common/ Usual Name	Patient Physiological Monitor (with Arrhythmia Detection or Alarms)
Classification	Monitor, Physiological, Patient (with Arrhythmia Detection or Alarms) 870.1025 MHX Oximeter 870.2700 DQA

Electrocardiograph
870.2340
DPS

Monitor, ST Segment with Alarm
870.1025
MLD

Alarm, Blood Pressure
870.1100
DSJ

Plethysmograph, Impedance
870.277
DSB

System, Network and Communication, Physiological Monitors
870.23
MSX

Arrhythmia detector and alarm (incl. ST-segment measurement & alarm)
DSI / 870.1025

Note: There are no previous submissions for this device

3. Predicate Device to which this is Substantially Equivalent

Surveyor S12 and S19 Patient Monitor	K123556
Intellivue Patient Monitor Model MX800	K102562

The S12/S19 was last recalled in 2014, Z-0110-2015. There are no open recalls for the S12/S19 Patient Monitor.

The Intellivue Patient Monitor Model MX800 was last recalled in 2012, Z-1134-2012.

4. Device Description

The Mortara Surveyor S12 and S19 are integrated multi-parameter patient monitors designed to be used by trained medical personnel within healthcare facilities on adult, adolescent, child, infant, and neonatal patient populations.

Surveyor S12 and S19 include color, touch screen displays which present patient demographics, physiological waveforms, numeric data, trends, status condition, with high, medium, and low warning alarms and technical messages. The monitor alerts of patient conditions with audible alarming through a speaker located within the device, visual alarms presented on the graphical user interface, and a visual LED alarm bar indicator on the front of the unit. The monitor provides a dedicated ON/OFF switch with AC power LED indication. Power is provided either from an external power supply connected to mains, or an internal lithium-ion battery. The Surveyor S12 has an 11.6" display and comes with an integrated 2 channel printer, while the Surveyor S19 has at 18.5"display and comes with an optional 2 channel printer.
The Surveyor S12 and S19 are intended for continuous monitoring in both bedside and portable applications and are manufactured in various fixed configurations. A Surveyor S12 or S19 may include the following parameters: 3, 5, or 10 Wire electrocardiography (ECG), 12 lead resting ECG, impedance respiration, non-invasive blood pressure (NIBP), up to two temperatures, functional arterial oxygen saturation (SpO_2), up to four invasive blood pressures (IBP), end-tidal & inspired CO_2, and thermal dilution cardiac output.

The Surveyor S12 and S19 may be used as stand-alone monitors near the patient bedside, or during patient transport within a healthcare facility. When connected to the Mortara Surveyor Network, the Surveyor S12 and S19 can be part of a centralized monitoring system managed by the Surveyor Central Station (K131929) which can also send data to the Electronic Health Record. The Surveyor Central displays the aforementioned parameters including audible and visuals alarms.

Parameters by Patient Type

Parameter	Patient Types		
	Adult	Pediatric Adolescent/Child/Infant	Neonate
ECG 3-Lead	✓	✓	✓
ECG 5-Lead	✓	✓	✓
ECG 12-Lead	✓	✓	✓
Resting 12 Lead Interpretation	✓	✓	✓
ST Segment Monitoring	✓	✓	N/A
Respiration - Impedance	✓	✓	✓
Respiration- Capnography	✓	✓	✓

NIBP (Non-Invasive Blood Pressure)	✓	✓	✓
SpO2- Mortara	✓	✓	N/A
SpO2- Nellcor Oxi-Max	✓	✓	✓
CO2	✓	✓	✓
IBP (Invasive Blood Pressure)	✓	✓	✓
Cardiac Output	✓	✓	N/A
Temperature	✓	✓	✓
Arrhythmia Basic	✓	✓	✓
Arrhythmia Extended	✓	✓	✓

5. Intended Use

The Mortara Surveyor Patient Monitor is indicated for use in adult, adolescents and children patient populations for the monitoring of the following parameters:

- Non-invasive blood pressure
- Impedance respiration
- Invasive blood pressure
- Temperature
- Functional arterial oxygen saturation (SpO_2)End-tidal & inspired CO_2
- ECG monitoring with arrhythmia & ST-segment
- 12-Lead resting ECG
- Cardiac output

The Mortara Surveyor Patient Monitor is indicated for use in infants and neonatal patient populations for the monitoring of the following parameters:

- Non-invasive blood pressure
- Impedance respiration
- Invasive blood pressure
- Temperature
- Functional arterial oxygen saturation (SpO_2)End-tidal & inspired CO_2
- ECG monitoring with arrhythmia
- 12-Lead resting ECG

The Mortara Surveyor Patient Monitor is a prescription device intended to be used by healthcare professionals in all areas of a healthcare facility.

6. Technological characteristics

The Surveyor S12 and S19 Patient Monitor employs the same functional scientific technology as its predicate devices Surveyor S12 and S19 Patient Monitor (K123556), and Philips Intellivue Patient Monitor Model MX800 (102562). At a high level, the devices provide continuous monitoring for ECG, Respiration, NIBP, Temperature, SPO2, Invasive Blood Pressure, End-Tidal & Inspired CO2, 12-lead resting ECG and cardiac output.

Surveyor S12 and S19 Patient Monitor was designed and manufactured by Mortara Instrument according to 21 CFR Part 820. Surveyor S12 and S19 Patient Monitor is substantially equivalent to Surveyor S12 and S19 Patient Monitor (Predicate K123556) with the following technological differences:

- Added Neonates to the target population
- Modifications were made to the AM12
- Added 10-Wire Snap Ends leads for AM12
- Adjusted display of alarm priority level on Arrhythmia settings page
- Improved impedance resistor and capacitor value changes
- Added ECG Trunk Cables
- Software update to allow printing of displayed trends upon request of user
- Improved tolerance when using 3/5-wire ECG with high impedance electrodes
- Added a product configuration without Invasive Blood Pressure
- Software correction of technical error message when the NIBP port/hose is occluded
- Improve recovery from standby of the communication with central station
- Communication to third party software through the serial port

A full comparison matrix of functionality is located in Section 12, Substantial Equivalence Discussion.

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 for Premarket Submissions for Software Contained in Medical Devices"* and *"Off-the-Shelf Software Use in Medical Devices."*

S12/S19 was designed and tested for compliance with the applicable clauses of the following standards:

- UL 60601-1 Issued: 2003/04/25 Ed: 1 Rev: 2006/04/26 Medical Electrical Equipment - Part 1: General Requirements for Safety
- IEC 60601-1: 2005 Ed:3 Medical electrical equipment Part 1: General requirements for basic safety and essential performance; Corr. 1: 2006, Corr. 2: 2007
- IEC 60601-1-4 Issued 2000/04/01 Ed 1.1 Medical electrical systems – Part 1-4: General requirements for safety – Collateral standard: Programmable electrical medical systems
- IEC 60601-1-6 Issued: 2006/12/08 2nd Ed. Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 62366 Issued: 2007/10/18 Ed. 1 Medical Devices - Application Of Usability Engineering To Medical Devices
- IEC 60601-1-8 Issued: 2006/10/25 Ed: 2 Medical Elec. Equip. – Part 1-8: General Req. for Basic Safety & Essential Perf. – Collateral Standard: General Req., Tests & Guidance for Alarm Systems in Medical Elec. Equip. & Medical Elec. Systems
- IEC 60601-2-27 Issue:2011/03/30 Ed:3 Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment
- IEC 60601-1-4 Issued 2000/04/01 Ed 1.1 Medical electrical systems – Part 1-4: General requirements for safety – Collateral standard: Programmable electrical medical systems
- IEC 60601-2-30 Issued:1995/01/01 Ed:1 Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Automatic Cycling Indirect Blood Pressure Monitoring Equipment-First Edition
- IEC 80601-2-30 Issued: 2009/01/28 Ed: 1 Medical Electrical Equipment - Part 2-30: Particular Requirements for the Basic Safety and Essential

Performance of Automated Non-Invasive Sphygmomanometers; Corr. 1: 2010

- IEC 60601-2-34 Issue:2011/05/19 Ed:3 Medical Electrical Equipment Part 2-34: Particular Requirements for the Safety, Including Essential Performance, of Invasive Blood Pressure Monitoring Equipment
- IEC 60601-2-49 Issued:2011/02/25 Ed:2 Medical Electrical Equipment - Part 2-49: Particular Requirements for the Safety of Multifunction Patient Monitoring Equipment
- ISO 80601-2-55 Issued: 2011/12/15 Ed:1 Medical electrical equipment – Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
- ISO 80601-2-56 Issue:2009/10/01 Ed:1 Medical Electrical Equipment - Part 2-56: Particular Requirements for the Basic Safety and Essential Performance of Clinical Thermometers for Body Temperature Measurement
- ISO 80601-2-61 Issued: 2011/04/01 Ed:1 Medical Electrical Equipment - Part 2-61: Particular Requirements for the Basic Safety and Essential Performance of Pulse Oximeter Equipment
- ISO 9919 Issued:2005/03/15 Medical electrical equipment Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
- IEC 60601-2-25:2011 Ed. 2.0, Medical Electrical Equipment. Part 2-25: Particular requirements for the basic safety and essential requirements of electrocardiographs
- IEC 60601-1-2: 2007 Medical Electrical Equipment – Part 1-2: General requirements for safety- Collateral standard: Electromagnetic Compatibility
- IEC 62304:2006 Medical device software – Software life cycle process
- ANSI/AAMI/ISO EC57:1998/(R)2008 Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms
- ANSI/AAMI/ISO 81060-2:2013, Noninvasive sphygmomanometers – Part 2: Clinical investigation of automated measurement type

8. Determination of Substantial Equivalence – Clinical

A clinical study was conducted to demonstrate the safety and effectiveness of Non-Invasive Blood Pressure readings for the neonatal patient population, per ISO 81060-2:2013 and ISO 14155:2011.

9. Conclusion

The Surveyor S12 and S19 Patient Monitor includes Non-Invasive Blood Pressure for the neonatal patient population.

Mortara Instrument, Inc. considers the Surveyor S12 and S19 Patient Monitor to be as safe, as effective and performance is substantially equivalent to the predicate devices.