September 4, 2018

Mortara Instrument, Inc.
Manisha Gokuli
Regulatory Affairs Manager
7865 North 86th Street
Milwaukee, Wisconsin 53224

Re: K173765
Trade/Device Name: Surveyor 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, DSB, MSX, DSI, DSJ
Dated: December 7, 2017
Received: December 11, 2017

Dear Manisha Gokuli:

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,

Arielle Drummond -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)*

K173765

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 parameters:

* 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 (SpO2)
* End-tidal & inspired CO2
* ECG monitoring with arrhythmia
* 12-Lead resting ECG

The 'Bed to Bed communication' feature allows remote viewing of monitors when connected to a Surveyor Central Station.

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.

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Traditional 510(k) Notification

Section 5

510(k) Summary

1. Submitter

Date: 10/17/2017

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Fax 414-354-4760

Primary Contact

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VP Global RA/QA
Mark.Elliott@mortara.com

2. Product Names

Device Trade Name	Surveyor 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
870.2770
DSB

System, Network and Communication, Physiological Monitors
870.2300
MSX

Detector and Alarm, Arrhythmia
870.1025
DSI

3. Predicate Device to which this is Substantially Equivalent

Predicate Device	Name	510(k) Number
Primary	Surveyor Patient Monitor	K161517
Secondary	Philips Intelliview Patient Monitor MX800	K161531

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 July 26, 2016, Z-2328-2016.

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.

The new Surveyor S12, S19, V3.0.1 has added Wireless LAN capability and a Bedside-to-Bedside (B2B) feature that allows remote viewing of monitors when connected to a Surveyor Central Station

Parameters by Patient Type

Parameters	Patient Types		
	Adult	Pediatric Adolescent/Children	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

Indications for 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 (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 (SpO2)
- ✓ End-tidal & inspired CO2
- ✓ ECG monitoring with arrhythmia
- ✓ 12-Lead resting ECG

The ‘Bed to Bed communication’ feature allows remote viewing of monitors when connected to a Surveyor Central Station.

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 v2.0.0 (K161517) and Philips MX800 Patient Monitor (K161531). 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 v3.1.0 was designed and manufactured by Mortara Instrument according to 21 CFR Part 820. Surveyor S12 and S19 Patient Monitor v3.1.0 is substantially equivalent to Surveyor S12 and S19 Patient Monitor v2.0.0 (Primary Predicate K161517), which is in commercial distribution, except for the following new features that were added:

- Wireless LAN capability
- Bedside-to-Bedside (B2B) Feature: The 'Bed to Bed communication' feature allows remote viewing of monitors when connected to a Surveyor Central Station.

A second predicate device used for this submission is Philips MX800 Patient Monitor (K161531), and has a feature 'Bed-to-bed overview', that provides clinicians with an overview of all the patient beds in their care. This feature is similar to the 'Bedside-to-Bedside (B2B) Feature' that is in the submitted device.

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

Comparison Matrix

For detailed comparisons refer to the Table 12-1.

Table 12-1 Comparison Matrix to Predicate Device

	Predicate Device 1 (Primary) Surveyor S12 and S19 Patient Monitor	**Predicate Device 2 (Secondary) Philips MX800 Patient Monitor**	**Present Submission Surveyor S12 and S19 Patient Monitor**	**Change explanation for the subject device**
510(k)	K161517	K161531	Present Submission	
BRAND	Surveyor S12/S19	Philips MX800	Surveyor S12/S19	
COMPANY	Mortara Instrument, Inc.	Philips Medical Systems	Mortara Instrument, Inc.	
Software Version	V2.0.0		V3.1.0	
Indications for 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	The Philips MX800 is indicated for Adult, Pediatric or Neonatal) for the monitoring of the following parameters: • Non-invasive blood pressure • Impedance respiration • Invasive blood	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-	Added

	• 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	pressure • Temperature • Functional arterial oxygen saturation (SpO_2) • End-tidal & inspired CO_2 (with MMS extension) • ECG monitoring with arrhythmia & ST-segment • Cardiac output	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: • ion-invasive blood pressure • Impedance respiration • Invasive blood pressure • Temperature • Functional arterial oxygen saturation (SpO_2) End-tidal & inspired CO_2 • ECG monitoring with arrhythmia The 'Bed 2 Bed communication' feature allows remote viewing of monitors when connected to a Surveyor Central Station. The Mortara Surveyor Patient Monitor is a prescription device intended to be used by healthcare professionals in all areas of a healthcare facility.	

	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 restin			

	g ECG The Mortar a Surve yor Patien t Monit or is a prescr iption device intend ed to be used by health care profes sional s in all areas of a health care facility .			

Bedside to Bedside (B2B) Feature	None	Bed-to-bed overview provides clinicians with an overview of all the patient beds in their care (Reference: Philips_IntelliVue_MX800_Technical_Datasheet).	The 'Bed to Bed communication' feature allows remote viewing of monitors when connected to a Surveyor Central Station. The Remote View and Notification features are enabled on a Unit by Unit basis.	Added
Viewing the Other Bed Window	NA	The other Bed Window lets you view a subset of the waveform and numeric information from another bed on the same network – Reference Page 125 Instructions for USE 4535644175 61(Eng)	The 'Bed to Bed communication' feature if enabled, allows remote viewing of other patient monitor limited information when connected to a Surveyor Central Station.	Added

Alarm occurrence at another Bed	NA	• The other Bed window can be configured to pop-up automatically when an alarm occurs at another Bed. • This automatic pop-up can be temporarily disabled.	When the 'Bed to Bed communication' feature is enabled and the Alarm Notification is set to ON, it allows the notification of alarm at another bed in B2B window.	Added
Accessing remote patient limited information	NA	• Overview BAR next to the Monitor's own Bed Label • To Open the Other Bed Window, select the required bed label or patient name in the Alarm Status Overview Bar • If you are in a Unit Group with many beds, the 'MY Patients window may open for you to select the bed.	• Touching the Remote View button displays the Setup Remote View menu and the Bed list. The user can select any bed on the list to open the Remote view for the Bed.	Added

Connects Hospital Intranet to retrieve other Patient information/data	NA	Yes	Yes	Equivalent
Processor Board	Z1		Z2	Equivalent
Network interface, wired	IEEE 802.3 Ethernet, 10/100 Mbps	IEEE 802.3 Ethernet, 100 Mbps	IEEE 802.3 Ethernet, 10/100 Mbps	Identical
Network interface, wireless	None	IEEE 802.11a/b/g 2.4 GHz and 5 GHz Band	Wireless LAN	Added
Network system compatibility	Mortara Surveyor Network	The integrated PC (iPC) allows access to relevant patient information residing on the hospital's intranet. (Reference: Datasheet)	Mortara Surveyor Network	Identical
Serial interface	RS-232	IEEE 1073-3.2-2000 Connectors RJ45 (8 pin)	RS-232	Identical
Target Population	Adult, adolescents, children, infants and neonatal patient populations	Adult, pediatric, neonatal	Adult, adolescents, children, infants and neonatal patient populations	Identical
Operating Modes	Continuous Monitoring	Continuous Monitoring	Continuous monitoring	Identical

12 Lead ECG	ECG acquisition module model AM12M with snap end lead set	X1 multi measurement module for 12-lead ECG	ECG acquisition module model AM12M with snap end lead set	Identical
ECG cable set for 3/5-wire applications	Integrated cables and trunk cable with detachable lead sets (including for Neonatal applications).	X1 multi measurement module for 3/5 wire ECG	Integrated cables and trunk cable with detachable lead sets (including for Neonatal applications).	Identical
ECG input impedance	>2.5 MOhm at 10 Hz	>2 MOhm RA-LL leads (Resp) >5 MOhm at all other leads (at 10 Hz including patient cable)	>2.5 MOhm at 10 Hz	Equivalent
3/5 wire ECG lead fail detection	Active electrode: <100 nA Reference electrode: <900 nA	Active electrode: <100 nA Reference electrode: <900 nA	Active electrode: <100 nA Reference electrode: <900 nA	Identical
Alarm Levels	High, medium, low; visually color-coded & audible, complies with IEC 60601-1-8	High, medium visually color-coded & audible	High, medium, low; visually color-coded & audible, complies with IEC 60601-1-8	Identical
Alarm on off can be done by manual control on the device or remotely	Alarm on the Device can be silenced only on the device or from Surveyor Central	Alarm on/off can be done on the device only	Alarm on the Device can be silenced only on the device or from Surveyor Central	Identical
Response to controls:	Power on/off is on the Device	Power on/off is on the Device	Power on/off is on the Device	Identical

Trending	Up to 72 hours of parameter information, available in 1/5/15/60/240 min. averaged intervals	8 hours trend data at 1-minute resolution in module X1, 24 hours in module X2	Up to 72 hours of parameter information, available in 1/5/15/60/240 min. averaged intervals	Identical
Compatible Systems	Surveyor Central Station (K131929)	IntelliVue Information Center (K143057)	Surveyor Central Station (K131929)	Identical
Measurement Method	Oscillometric	Oscillometric	Oscillometric	Identical
Measurement Units	mmHg	mmHg	mmHg	Identical
Measurement Mode	Auto or manual	Auto or manual	Auto or manual	Identical
Cuff Size	Infant, Child, Small Adult, Regular Adult, Large Adult, Thigh	Adult (thigh), Large Adult, Adult, Small Adult, Pediatric, Infant	Neonate, Infant, Child, Small Adult, Regular Adult, Large Adult, Thigh	Identical
Measurement method	Thoracic impedance plethysmography	Thoracic impedance plethysmography	Thoracic impedance plethysmography	Identical
Input	3 or 5-Lead ECG cable	3, 5, 6 or 10-lead ECG Cable	3 or 5-Lead ECG cable	Identical
Respiration Signal	Measured between the RA and LL electrodes	Measured between the RA and LL electrodes	Measured between the RA and LL electrodes	Identical
Respiration Rate Resolution	1 bpm (breaths per minute)	1 bpm (breaths per minute)	1 bpm (breaths per minute)	Identical
Bandwidth	0.17 to 3.3 Hz (-3dB)	0.3 to 2.5 Hz (-6 dB)	0.17 to 3.3 Hz (-3dB)	Equivalent

Measurement method	Direct measurement of arterial or venous pressure via transducer	Direct measurement of arterial or venous pressure via transducer	Direct measurement of arterial or venous pressure via transducer	Identical
Pressure sources	ART, CVP, ICP, LA, P1, P2, P3, P4, PAWP, RA, PA, UAP, UVP	ABP,ART,Ao,CVP,ICP,LAP,P,PAP,RAP,UAP,UVP	ART, CVP, ICP, LA, P1, P2, P3, P4, PAWP, RA, PA, UAP, UVP	Identical
Product Configurations with IBP	Marketed configurations include 2 IBP channels, 4 IBP channels, and no IBP channels.	2 x IBP channels. Additional channels may be added through modules	Marketed configurations include 2 IBP channels, 4 IBP channels, and no IBP channels.	Identical
Measurement method	Direct, continuous	Direct, continuous	Direct, continuous	Identical
Probe Type	400-series temperature sensor with ¼ inch phone plug	400-series temperature sensor with ¼ inch phone plug	400-series temperature sensor with ¼ inch phone plug	Identical
Measurement Method	Pulse oximetry, optical	Pulse oximetry, optical	Pulse oximetry, optical	Identical
Measurement algorithm	Mortara SpO_2, Nellcor OxiMax	Philips, Nellcor, Masimo	Mortara SpO_2, Nellcor OxiMax	Identical
Parameters	% SpO_2, pulse rate, plethysmogram	% SpO_2, pulse rate, plethysmogram, perfusion value	% SpO_2, pulse rate, plethysmogram	Identical
Method	Capnography, non-dispersive infrared spectroscopy, continuous	Capnography, non-dispersive infrared spectroscopy, continuous	Capnography, non-dispersive infrared spectroscopy, continuous	Identical
Algorithm	Veritas	Oridion Microstream	Veritas	Equivalent

Sampling configurations	Sidestream	Mainstream, sidestream, microstream	Sidestream	Identical
Measurements	End-tidal CO_2 ($EtCO_2$), Fractional Inspired CO_2 ($FiCO_2$), Respiration Rate (RR-CO_2), Integrated Pulmonary Index (IPI)	CO2 waveform, End Todal CO2 (etCO2), Inspired Minimum CO2 (iMCO2), airway respiration rate (awRR), Integrated Pulmonary Index (IPI),	End-tidal CO_2 ($EtCO_2$), Fractional Inspired CO_2 ($FiCO_2$), Respiration Rate (RR-CO_2), Integrated Pulmonary Index (IPI)	Identical
Type	Color LCD	Color LCD	Color LCD	Identical
Size	S12: 11.6” S19: 18.5”	19”	S12: 11.6” S19: 18.5”	Identical
Input methods	Touchscreen	Touchscreen	Touchscreen	Identical
Power sources	Mains AC, 100-240 V, 50/60 Hz; or internal battery	Mains AC, 100-240 V, 50/60 Hz; or user replaceable internal battery	Mains AC, 100-240 V, 50/60 Hz; or internal battery	Identical
Battery Type	Internal lithium-ion rechargeable	Internal lithium-ion rechargeable	Internal lithium-ion rechargeable	Identical
Degree of protection	Type CF applied parts	Type CF applied parts	Type BF and CF applied parts	Identical

Intended operating environment	Temp: +32 to +104 °F Humidity: 15 to 90%	0 to 40 ºC (32 to 104 ºF) 0 to 35°C (32 Operating 15% to 95% Relative Humidity (RH) (non condensing) Storage 5% to 95% Relative Humidity (RH) (non condensing)	Temp: +32 to +104 °F Humidity: 15 to 90%	Identical
Mode of operation	Continuous	Continuous	Continuous	Identical
Ingress Protection	IPX1 (drip-proof)	IPX1	IPX1	Identical
User Interface Selection Options	N/A	N/A	• Ability to select detection leads • Ability to select QRS amplitude threshold	Added
Data logging	Veritas QRS labels on Bedside Monitor data storage	N/A	Veritas QRS labels on Bedside Monitor data storage or connected Surveyor Central System data storage	Added
Pacemaker Detection	Pacemaker detection selectable from Bedside Monitor	N/A	Pacemaker detection selectable from Bedside Monitor or connected Surveyor Central System	Added
ST Analysis	Partial support of ST Analysis features on connected Surveyor Central System	N/A	Full support of ST Analysis features on connected Surveyor Central System	Added
Trend Reports	Trend reports available on Bedside Monitor	N/A	Trend reports available on Bedside Monitor or connected Surveyor Central System	Added

Demographic data editing	N/A	N/A	Demographic data can be updated through serial communication	Added

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:

IEC 60601-1:2005 Ed:3 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2007 Medical Electrical Equipment – Part 1-2: General requirements for safety – Collateral Standard: Electromagnetic Compatibility
IEC 60601-1-8:2006 Medical Electrical Equipment -- Part 1-8: General requirements for basic safety and essential performance -- Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-2-25 Edition 2.0 2011-10: Medical Electrical Equipment - Part 2-25: Particular Requirements For The Basic Safety And Essential Performance Of Electrocardiographs
IEC 60601-2-27:2011 Ed:3 Medical Electrical Equipment PT. 2: Particular Requirements for the Safety, including essential performance, of Electrocardiographic Monitoring Equipment
IEC 60601-2-34:2011 Ed:3 Medical Electrical Equipment Part 2-34: Particular Requirements for the Safety, Including Essential Performance, of Invasive Blood Pressure Monitoring Equipment
IEC 62366:2007 Medical Devices -- Application of usability engineering to medical devices
ISO 80601-2-30:2009 Ed: 1.1 Medical Electrical Equipment - Part 2-30: Particular Requirements for the Basic Safety and Essential Performance of Automated Non-Invasive Sphygmomanometers; Corr. 1: 2010
ISO 80601-2-55:2011 Medical electrical equipment Particular requirements for the basic safety and essential performance of respiratory gas monitors
ISO 80601-2-56:2009 - Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
ISO 80601-2-61:2011 - Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
AAMI ANSI EC 57:2012 Testing And Reporting Performance Results Of Cardiac Rhythm And ST-Segment Measurement Algorithms
IEC 62304:2006; Medical device software -- Software life cycle processes

8. Conclusion

The new/submitted Surveyor S12 and S19 Patient Monitor has added

- Wireless LAN capability
- Bedside-to-Bedside (B2B) Feature: The ‘Bed to Bed communication’ feature allows remote viewing of monitors when connected to a Surveyor Central Station.

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