DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 23, 2017

Shenzhen Mindray Bio-medical Electronics Co., LTD.
Yanhong Bai
Manager Regulatory Affairs
Mindray Building, Keji 12th Road South
Hi-tech Industrial Park, Nanshan
Shenzhen, 518057, P.R. China

Re: K170876
Trade/Device Name: Passport Series Patient Monitors (Passport 12m, Passport 17m)
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm
Regulatory Class: Class II
Product Code: MHX, DSI, MLD, DRT, DXN, DSK, FLL, DQA, DPZ, CCK, CBQ, CBS, CBR, CCL, DSB, DXG, OLW, DSJ, KOI, GXY
Dated: July 14, 2017
Received: July 17, 2017

Dear Yanhong Bai:

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 (DICE) 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 (DICE) 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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170876

Device Name
Passport Series Patient Monitors (Passport 12m and Passport 17m)

Indications for Use *(Describe)*

The Passport 17m and Passport 12m patient monitors are intended for monitoring, displaying, reviewing, alarming, and transferring of multiple physiological parameters including ECG (3-lead , 5-lead or 12-lead selectable, arrhythmia detection, ST segment analysis, QT analysis, and heart rate (HR)), respiration rate (Resp), temperature (Temp), pulse oxygen saturation (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure(IBP), pulmonary artery wedge pressure (PAWP), cardiac output (C.O.), continuous cardiac output (CCO), mixed/central venous oxygen saturation (SvO2/ScvO2), carbon dioxide (CO2), Oxygen (O2), anesthetic gas (AG), impedance cardiograph (ICG), bispectral index (BIS), respiration mechanics (RM), and neuromuscular transmission monitoring (NMT). The equipment also provides an interpretation of resting 12-lead ECG.

All the parameters can be monitored on single adult, pediatric, and neonatal patients with the exception of the following:
- The arrhythmia detection, ST Segment analysis of Mortara algorithm, BIS, RM, CCO, SvO2/ScvO2, PAWP monitoring and NMT monitoring are intended for adult and pediatric patients only;
- ST Segment analysis of Mindray algorithm is intended for adult patients only;
- C.O. monitoring is restricted to adult patients only;
- ICG monitoring is only for use on adult patients who meet the following requirements: height: 122 to 229cm, weight: 30 to 155kg.

The monitor is to be used in healthcare facilities by clinical professionals or under their guidance. It should only be used by persons who have received adequate training in its use. It is not intended for helicopter transport, hospital ambulance, or home use.

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

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Passport Series Patient Monitors is provided below.

Device Common Name: Patient Monitor

Device Proprietary Name: Passport Series Patient Monitors (Passport 12m and Passport 17m)

Submitter:

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Date Prepared:

March 17, 2017

Classification Regulation: 21 CFR 870.1025, Class II, Arrhythmia detector and alarm (including ST-segment measurement and alarm)

Panel: Cardiovascular

Classification Regulation, Classification Name and Product Codes:

Product Code	Regulation Number	Panel	Regulation description	Device Common Name
Primary				
MHX	21 CFR 870.1025	Cardiovascular	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	monitor, physiological, patient(with arrhythmia detection or alarms)
Secondary				
Product Code	**Regulation Number**	**Panel**	**Regulation description**	**Device Common Name**
DSI	21 CFR 870.1025	Cardiovascular	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	detector and alarm, arrhythmia
MLD	21 CFR 870.1025	Cardiovascular	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	monitor, st segment with alarm
DRT	21 CFR 870.2300	Cardiovascular	Cardiac Monitor (including cardiotachometer and rate alarm)	monitor, cardiac (incl. cardiotachometer & rate alarm)
DXN	21 CFR 870.1130	Cardiovascular	Noninvasive blood pressure measurement system	system, measurement, blood-pressure, non-invasive
DSK	21 CFR 870.1110	Cardiovascular	Blood pressure computer	computer, blood-pressure
FLL	21 CFR 880.2910	Cardiovascular	Clinical electronic thermometer	thermometer, electronic, clinical
DQA	21 CFR 870.2700	Cardiovascular	Oximeter	oximeter
DPZ	21 CFR 870.2710	Cardiovascular	Ear oximeter	oximeter, ear
CCK	21 CFR 868.1400	Anesthesiology	Carbon dioxide gas analyzer	analyzer, gas, carbon-dioxide, gaseous-phase
CBQ	21 CFR 868.1500	Anesthesiology	Enflurane gas analyzer	analyzer, gas, enflurane, gaseous-phase (anesthetic concentration)

CBS	21 CFR 868.1620	Anesthesiology	Halothane gas analyzer	analyzer, gas, halothane, gaseous-phase (anesthetic conc.)
CBR	21 CFR 868.1700	Anesthesiology	Nitrous oxide gas analyzer	analyzer, gas, nitrous-oxide, gaseous phase (anesthetic conc.)
CCL	21 CFR 868.1720	Anesthesiology	Oxygen gas analyzer	analyzer, gas, oxygen, gaseous-phase
DSB	21 CFR 870.2770	Cardiovascular	Impedance plethysmograph	plethysmograph, impedance
DXG	21 CFR 870.1435	Cardiovascular	Single-function, preprogrammed diagnostic computer	computer, diagnostic, pre-programmed, single-function
OLW	21 CFR 882.1400	Neurology	Electroencephalograph	index-generating electroencephalograph software
DSJ	21 CFR 870.1100	Cardiovascular	Blood pressure alarm	alarm, blood-pressure
KOI	21 CFR 868.2775	Anesthesiology	Electrical peripheral nerve stimulator	stimulator, nerve, peripheral, electric
GXY	21 CFR 870.1320	Neurology	Cutaneous electrode.	electrode, cutaneous

Primary Predicate Device: K152902 - Passport Series Patient Monitors (Passport 12m, Passport 17m, and T1); Shenzhen Mindray Bio-Medical Electronics Co., Ltd

Secondary Predicate Device:
K161531 - IntelliVue Patient Monitors (Philips Medizin Systeme Boeblingen GmbH)

Indications for Use:

The Passport 17m and Passport 12m patient monitors are intended for monitoring, displaying, reviewing, alarming, and transferring of multiple physiological parameters including ECG (3-lead, 5-lead or 12-lead selectable, arrhythmia detection, ST segment analysis, QT analysis, and heart rate (HR)), respiration rate (Resp), temperature (Temp), pulse oxygen saturation (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure(IBP), pulmonary artery wedge pressure (PAWP), cardiac output (C.O.), continuous cardiac output (CCO), mixed/central venous oxygen saturation (SvO2/ScvO2), carbon dioxide (CO2), Oxygen (O2), anesthetic gas (AG), impedance cardiograph (ICG), bispectral index (BIS), and

respiration mechanics (RM), neuromuscular transmission monitoring(NMT). The equipment also provides an interpretation of resting 12-lead ECG.

All the parameters can be monitored on single adult, pediatric, and neonatal patients with the exception of the following:

- The arrhythmia detection, ST Segment analysis of Mortara algorithm, BIS, RM, CCO, SvO2/ScvO2, PAWP monitoring and NMT are intended for adult and pediatric patients only;
- ST Segment analysis of Mindray algorithm is intended for adult patients only;
- C.O. monitoring is restricted to adult patients only;
- ICG monitoring is only for use on adult patients who meet the following requirements: height: 122 to 229cm, weight: 30 to 155kg.

The monitor is to be used in healthcare facilities by clinical professionals or under their guidance. It should only be used by persons who have received adequate training in its use. It is not intended for helicopter transport, hospital ambulance, or home use.

Device Description:

The subject Passport Series Patient Monitors includes two monitors:

- Passport 12m Patient Monitor
- Passport 17m Patient Monitor

The Passport 12m and 17m Patient monitors provide patient monitoring capabilities based on the user selected modules that are plugged into the main monitor.

Performance Data:

- To establish the substantial equivalence of the Passport Series Patient Monitors (Passport 12m and Passport 17m), Mindray conducted functional and system level testing on the subject devices. The testing provided an evaluation of the performance of the device relevant to each of the modifications to the subject devices since their previous clearance. The functional and system level testing showed that the devices continue to meet specifications and the performance of the device is equivalent to the predicate.
- In addition, Mindray has conducted testing to ensure the subject devices meet relevant consensus standards.
  - IEC 60601-1:2005+A1:2012 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 basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
  - IEC 60601-2-10:2012 Medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
  - 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

- ISO 80601-2-55:2011 Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors

Substantial Equivalence:

Comparison of Indications - Both the predicate device and the subject Passport 12m and Passport 17m devices are multiparameter patient monitors intended to be used in healthcare facilities under the direction of clinical professionals. The indications for use of the subject devices (Passport 12m and Passport 17m) have been modified to include the new module of NMT. Although this feature is not present in the predicate device, it is present in the cleared Philips (K161531), and thus does not constitute a new intended use for a multi-parameter monitor. In conclusion, the minor changes to the indications for use do not change the fundamental intended use of the Passport 12m and Passport 17m as multiparameter monitors.

Comparison of Technological Characteristics - The table below compares the key technological feature of the subject devices to the primary predicate device (Passport Series Patient Monitors K152902). The features in grey are the features that have been modified since their previous clearances and that are the subject of this 510(k).

Device Comparison Table (Compare with Passport 12m/17m (K152902))

	Predicate Device (K152902)		**Subject Devices**	
Feature	**Passport 17m**	**Passport 12m**	**Passport 17m**	**Passport 12m**
Integrated display and touchscreen	17” 1280*1024 pixels	12” 800*600 pixels	Same	Same
Secondary display	Independent control and display	Display is linked to integrated display	Same	Same
Additional display features	The minitrends diagram, OxyCRG diagram, other monitor view, and calculation can be viewed when using an external LCD screen		Same	Same

	Predicate Device (K152902)		Subject Devices	
Feature	**Passport 17m**	**Passport 12m**	**Passport 17m**	**Passport 12m**
Wireless module	The ASUS module is used for connecting to a network wirelessly, constructing a monitoring network with a central monitoring system (CMS).	The ASUS and Silex modules are used for connecting to a network wirelessly, constructing a monitoring network with a central monitoring system (CMS).	Same	Laird (2.4G/5G) wireless module is added.
Module rack	Independent of the patient monitor, provides 8 standard module slots to extend the measurement capabilities of the system		Same	
Power supply	Two rechargeable Lithium-ion battery or AC power supply	One rechargeable Lithium-ion battery or AC power supply	Same	Same
Battery	Chargeable Lithium-Ion, 11.1 VDC, 4500 mAh, 350 g		Same	
External memory card	Compact Flash		Same	
Data Recorder	The thermal recorder records patient information, measurement numerics, up to three waveforms, etc.		Same	
Speaker	Give alarm tones (45 to 85 dB), key tones, QRS tones; support PITCH TONE and multi-level tone modulation		Same	
Supports T1 as a module	Supported		Same	
ECG	3-lead , 5-lead or 12-lead selectable, arrhythmia detection, ST segment analysis, QT analysis, heart rate (HR), an interpretation of resting 12-lead ECG, J-point Auto detection, Dual Channel Pace detection and Adjustable QRS Detection Threshold		Same	
Arrhythmia Analysis (Mindray Algorithm)	Asystole, VFib/VTac, Vtac, Vent. Brady, Extreme Tachy, Extreme Brady, PVC, Couplet, Bigeminy, Trigeminy, R on T, Run PVCs, PVCs, Tachy, Brady, Missed Beats, Vent. Rhythm, PNP, PNC, Multif. PVC, Nonsus. Vtac, Pause, Irr. Rhythm, AFib		Same	
Arrhythmia Analysis (Mortara Algorithm)	Asystole, Vfib, Vtac, Vent. Rhythm, Couplet, Run PVCs, Bigeminy, Trigeminy, R on T, Multif. PVC, Irr. Rhythm, Tachy, Brady, Missed Beats, PNP, PNC, PVCs		Same	

	Predicate Device (K152902)		Subject Devices	
Feature	**Passport 17m**	**Passport 12m**	**Passport 17m**	**Passport 12m**
Respiration rate (Resp)	Measurement range: Adult: 0 to 120 rpm; Pediatric, neonate: 0 to 150 rpm. Accuracy: 7 to 150 rpm: ±2 rpm or ±2%, whichever is greater; 0 to 6 rpm: Not specified.		Same	
Temperature (Temp)	Measurement range: 0 to 50°C (32 to 122°F) Accuracy: ±0.1°C or ±0.2°F (without probe)		Same	
Pulse oxygen saturation (SpO_2)	Mindray SpO2 Module Measurement range: 0 to 100% Accuracy:70 to 100%: ±2% (adult/pediatric mode) 70 to 100%: ±3% (neonate mode) 0% to 69%: Not specified. Masimo SpO2 Module Measurement range: 1 to 100% Accuracy:70 to 100%: ±2% (measured without motion in adult/pediatric mode) 70 to 100%: ±3% (measured without motion in neonate mode) 70 to 100%: ±3% (measured with motion) 1% to 69%: Not specified. Nellcor SpO2 Module Measurement range: 0 to 100% Accuracy:70 to 100%: ±2% (adult/pediatric) 70 to 100%: ±3% (neonate) 0% to 69%: Not specified.		Same	

	Predicate Device (K152902)		Subject Devices	
Feature	**Passport 17m**	**Passport 12m**	**Passport 17m**	**Passport 12m**
Pulse rate (PR)	PR from Mindray SpO2 Module Measurement range: 20 to 254 bpm Accuracy:±3 bpm PR from Masimo SpO2 Module Measurement range: 25 to 240 bpm Accuracy:±3 bpm (measured without motion) ±5 bpm (measured with motion) PR from Nellcor SpO2 Module Measurement range: 20 to 300 bpm Accuracy:20 to 250 bpm: ±3 bpm 251 to 300 bpm, not specified PR from IBP Module Measurement range: 25 to 350 bpm Accuracy:±1 bpm or ±1%, whichever is greater"		Same	
Non-invasive blood pressure (NIBP)	Measurement range: Adult Pediatric Neonate Systolic: 40 to 270 40 to 200 40 to 135 Diastolic: 10 to 210 10 to 150 10 to 100 Mean: 20 to 230 20 to 165 20 to 110 Accuracy: Max mean error: ±5 mmHg Max standard deviation: 8 mmHg		Same	
Invasive blood pressure (IBP)	Measurement range: -50 to 300 mmHg Accuracy:±2% or ±1 mmHg, whichever is greater (without sensor)		Same	
Pulse Pressure Variation (PPV)	Supported feature of IBP		Same	
Cardiac output (C.O.)	The temperature change is displayed as a curve in the C.O. split screen, and the monitor calculates the C.O. value from this curve. The monitor is capable of storing 6 measurements.		Same	

	Predicate Device (K152902)		Subject Devices	
Feature	**Passport 17m**	**Passport 12m**	**Passport 17m**	**Passport 12m**
Continuous cardiac output (CCO)	CCO/SvO_2 interface module is used to interface with Edwards Vigilance II monitor / Vigileo Monitor which measures continuous cardiac output (CCO), mixed venous oxygen saturation (SvO_2) and central venous oxygen saturation ($ScvO_2$).		Same	
Central venous oxygen saturation ($ScvO_2$)	ScvO2 module is used to measure central venous oxygen saturation ($ScvO_2$).		Same	
Carbon dioxide (CO_2)	Sidestream CO2 Module: Measurement range: 0 to 99 mmHg Accuracy: 0 to 40 mmHg: ±2 mmHg 41 to 76 mmHg: ±5% of the reading 77 to 99 mmHg: ±10% of the reading Microstream CO2 Module: Measurement range: 0 to 99 mmHg Accuracy: 0 to 38 mmHg: ±2 mmHg 39 to 99 mmHg: ±5% of the reading ±5% of the reading+0.08% of (the reading-38) Mainstream CO2 Module: Measurement range: 0 to 150 mmHg Accuracy: 0 to 40 mmHg: ±2 mmHg 41 to 70 mmHg: ±5% of the reading 71 to 100 mmHg: ±8% of the reading 101 to 150 mmHg: ±10% of the reading		Same	
Anesthetic gas (AG)	The AG module analyzes gas samples from the patient and calculates CO2, O2, N2O and AA waves and related numerics, airway respiratory rate, and MAC (minimum alveolar concentration). Supports the 3-slot AG module.		Added support for the 2-slot AG module	

	Predicate Device (K152902)		**Subject Devices**	
Feature	**Passport 17m**	**Passport 12m**	**Passport 17m**	**Passport 12m**
Impedance cardiograph (ICG)	Measurement range: SV: 5 to 250 ml HR: 44 to 2m C.O. 1.4 to 15 L/min Accuracy: SV: Not specified. HR: ±2 bpm C.O. Not specified.		Same	
Bispectral index (BIS)	Measured parameters: EEG, BIS, BIS L, BIS R		Same	
Respiration mechanics (RM)	Measurement range: Adult: 0 to 120 rpm; Pediatric: 0 to 150 rpm. Accuracy: 7 to 150 rpm:±2 rpm or ±2%, whichever is greater; 0 to 6 rpm: Not specified."		Same	
NMT	Not supported		Added	

Device Comparison Table (Compare with Philips NMT module (K161531))

Feature	Secondary Predicate Device NMT (K152902)	Subject Mindray NMT in this 510(k)	Comparison System
Composition	Module and accessory cable	Module and accessory cable	Same
Intended use	The IntelliVue NMT Module is intended to be used as an objective neuromuscular transmission monitor, using accelerometry for measuring the muscle contraction following an electrical stimulation of a peripheral nerve. The NMT Module is intended to be used with adult and pediatric patients.	The neuromuscular transmission (NMT) module is intended to be used as an objective neuromuscular transmission monitor, using accelerometry for measuring the muscle contraction following an electrical stimulation of a peripheral nerve. The NMT module is intended to be used with adult and pediatric patients.	Same
Principle of measurement	Neuro Muscular Transmission (NMT) and its measurement enables the evaluation of muscle relaxation of patients under Neuromuscular Block by measuring the strength of muscle reaction after electrically stimulating the dedicated motor nerve. The NMT Monitor electrodes are placed on the patient's skin over the ulnar nerve, a controllable current source delivers stimulation pulses to two skin surface electrodes for the nerve stimulation, the muscle response is measured with an acceleration sensor.	Neuromuscular Transmission (NMT) module evaluates muscle relaxation of patients under neuromuscular block by measuring the strength of muscle reaction after electrically stimulating the dedicated motor nerve. The electrodes are placed on the patient's skin over ulnar nerve, a controllable current source delivers stimulation pulses to two skin surface electrodes for the nerve stimulation, and the muscle response is measured with an acceleration sensor.	Same

Feature	Secondary Predicate Device NMT (K152902)	Subject Mindray NMT in this 510(k)	Comparison System
Stimulation Output	Current pulse: 100, 200, or 300μs; monophasic rectangle pulse	Current Pulse: 100, 200 or 300μs; monophasic rectangle pulse; Pulse width Accuracy: ±10%	Same
	Current Range: 5 to 60 mA in increments of 5 mA	Current Range:0 - 60 mA in increments of 5 mA	the actual output current of the two sides are both 5 to 60 mA Same
	Current Accuracy: ± 5% or ± 2 mA, whichever is greater	Current Accuracy: ± 5% or ± 2 mA, whichever is greater	Same
	Max. Skin Resistance: 3 kOhm	Max. Skin Impedance: 3kohm	Same
	Max. Output Voltage:300 V	Max. output voltage: 300 V	Same
Stimulation Modes	● Single Twitch (Twitch); ● Train-Of-Four (TOF); ● Post-Tetanic Count (PTC); ● Double-Burst Stimulation (DBS)	● Single Twitch (ST); ● Train-Of-Four (TOF); ● Post-Tetanic Count (PTC); ● Double-Burst Stimulation (DBS)	Same
Performance Specifications	Single Twitch Stimulation Mode: Twitch: 0 to 200% Measurement interval: Manual, or 1s, 12s, 30s	Single Twitch Stimulation Mode: ST-Ratio: 0 to 200% Measurement interval: Manual, 1s, 10s, 20s	Different Measurement interval

Feature	Secondary Predicate Device NMT (K152902)	Subject Mindray NMT in this 510(k)	Comparison System
	Train-Of-Four Stimulation Mode: TOF Count (TOFcnt): 0 to 4 TOF Ratio (TOFrat): 5 to 150%– Measurement interval: Manual, or 12s, 30s, 1min, 5min, 10min, 15min, 30min, 60min	Train-Of-Four Stimulation Mode: TOF-Count: 0 to 4 TOF-Ratio：5 to 160% Measurement interval: Manual, 12s, 15s, 20s, 30s, 1min, 5min, 15min, 30min, 60min	Wider TOF-Ratio Range; Different Measurement interval
	Post-Tetanic-Count Stimulation Mode: PTC:0 to 20 Measurement interval: Manual	Post-Tetanic-Count Stimulation Mode: PTC: 0 to 20 Measurement interval: Manual	Same
	Double-Burst Stimulation Mode: Measurement interval: Manual	Double-Burst Stimulation Mode: Manual, 15s, 20s, 30s, 1min, 5min, 15min, 30min, 60min	More Measurement intervals

Substantial Equivalence Conclusion:

Based on the detailed comparison of specifications for each of the modifications to the primary predicate devices, Passport 12m and Passport 17m (K152902), the secondary predicate devices, IntelliVue Patient Monitors(K161531) , the performance testing results and conformance with applicable standards show that the Passport Series Patient Monitors (Passport 12m and Passport 17m) can be found substantially equivalent to the predicate devices.