DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 22, 2016

Edan Instruments, Inc.
% Doug Worth
Edan Medical
1200 Crossman Ave. Suite 200
Sunnyvale, California 94089

Re: K160981
Trade/Device Name: Patient Monitor, models elite V5, elite V6 and elite V8
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, DSI, DRT, CBQ, DXN, DSK, CBR, DQA, NHO, CBS, NHQ, NHP, CCK, DSB, CCL, BZQ, BZK, DPS, FLL, DRG, MLD
Dated: November 30, 2016
Received: November 30, 2016

Dear Doug Worth:

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)*
K160981

Device Name
Patient Monitor, models elite V5, elite V6 and elite V8

Indications for Use *(Describe)*
The monitors are intended to be used for monitoring, storing, and reviewing of, and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates. The monitors are intended for use by trained healthcare professionals in hospital environments.
The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO2), cardiac output (C.O.), anesthetic gas (AG), bispectral index (BIS), respiration mechanics (RM) and impedance cardiography (ICG).
BIS is intended for use on adult and pediatric patients.
ICG monitoring is intended for use on adults only.
The arrhythmia detection and ST Segment analysis are intended for adult patients.
The monitors are additionally intended for use during patient transport inside hospitals.
The monitors are not intended for MRI environments.

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

Prepared in accordance with the content and format regulatory requirements of 21 CFR Part 807.92

1. Submitter: Edan Instruments, Inc
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Contact person: Queena Chen
Preparing date: March 30, 2016

2. Device name and classification:

Device Name: Patient Monitor
Model: elite V5, elite V6, elite V8
Classification Name/ Product code:
870.1025 monitor, physiological, patient(with arrhythmia detection or alarms)/ MHX
870.1025 Detector and Alarm, Arrhythmia/ DSI
870.1025 Monitor, ST Segment with Alarm/ MLD
870.2300 Cardiac monitor (including cardiotachometer and rate alarm)/ DRT
870.1130 Non-Invasive blood pressure/ DXN
870.1110 Blood pressure computer/ DSK
880.2910 Clinical Electronic Thermometers-Temperature Monitor with Probe/ FLL
870.2700 Oximeter, Pulse/ DQA
868.1400 Carbon Dioxide Gas Analyzer/ CCK
868.1500 Analyzer, Gas, Enflurane, Gaseous-Phase (Anesthetic Concentration)/ CBQ
868.1500 Analyzer, Gas, Desflurane, Gaseous-Phase (Anesthetic Concentration)/NHO
868.1500 Analyzer, Gas, Isoflurane, Gaseous-Phase (Anesthetic Concentration)/NHQ
868.1500 Analyzer, Gas, Sevoflurane, Gaseous-Phase (Anesthetic Concentration)/NHP
868.1620 Halothane gas analyzer/ CBS
868.1700 Nitrous Oxide gas analyzer/ CBR
868.1720 Oxygen gas analyzer/ CCL

	870.2770 Impedance plethysmograph/ DSB 868.1850 Monitoring spirometer/ BZK 868.2375 Monitor, Breathing Frequency/BZQ 870.2340 Electrocardiograph/DPS 870.2910 Radiofrequency physiological signal transmitter and receiver/ DRG **Regulatory Class:** Class II
3.Premarket Notification Class III Certification and Summary	Not applicable, the subject device is Class II.
4. Predicate Device(s):	1) Edan Instruments, Inc. / Patient Monitor Model elite V8/ K120173 2) Shenzhen Mindray Bio-Medical Electronics Co., Ltd/ BeneView T8 /K092449. 3) Edan Instruments, Inc. / iM70/ K131971
5. Reason for Submission	Modification for previous product elite V8 and introduce two new models elite V5 and elite V6.
6. Pre-Submission, IDE	Not applicable, there is no prior submission.
7. Device Description:	V series Patient Monitor including elite V5, elite V6 and elite V8 which can perform long-time continuous monitoring of multiple physiological parameters. Also, it is capable of storing, displaying, analyzing and controlling measurements, and it will indicate alarms in case of abnormity so that doctors and nurses can deal with them in time. The V series Patient Monitor realize the monitoring of physiological parameters by configuration with different parameter modules which include SpO2 (pulse oxygen saturation, pulse rate and SpO2 plethysmogram) with EDAN SpO2 module or Nellcor SPO2 module, NIBP (systolic pressure, diastolic pressure, mean pressure and pulse rate), TEMP, ECG, RESP(respiration), CO2, IBP, C.O. and AG(anesthetic gas), RM(respiratory mechanics), BIS(bispectral index) and ICG(impedance cardiography). The above is the maximum configuration for V series Patient Monitor, the user may select different monitoring parameters in according with their requirements. elite V5 configures with 12.1-inch color TFT touch screen , elite V6 and elite V8 with same screen except different sizes

15-inch and 17-inch separately. Three models are all build-in Lithium-ion battery, support software upgrade online and networking.

8. Intended Use:

The monitors are intended to be used for monitoring, storing, and reviewing of, and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates. The monitors are intended for use by trained healthcare professionals in hospital environments.

The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO2), cardiac output (C.O.), anesthetic gas (AG), bispectral index (BIS), respiration mechanics (RM) and impedance cardiography (ICG).

BIS is intended for use on adult and pediatric patients.

ICG monitoring is intended for use on adults only.

The arrhythmia detection and ST Segment analysis are intended for adult patients.

The monitors are additionally intended for use during patient transport inside hospitals.

The monitors are not intended for MRI environments.

9. Predicate Device Comparison

The subject devices share the same characteristics in all items with the predicate device, concluding from using the same technology and principle. All the technological differences existed between the subject and predicate devices are only some performance parameters improvement, for example accuracy for RESP Module is better, minor differences on NIBP module, different measurement range, accuracy and Sample flow rate for CO_2 module and different Warm-up time, Sample flow rate, measurement range, accuracy for AG module. Please refer to the following tables for details.

Comparison to Primary Predicate elite V8

Item	Proposed device (elite V5, elite V6, elite V8)	Predicate device (elite V8)	Justification
K#	Current Submission	K120173	___
Intended use			
Description	The monitors are intended to be used for monitoring, storing, and reviewing of, and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates. The monitors are intended for use by trained healthcare professionals in hospital environments. The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO2), cardiac output (C.O.), anesthetic gas (AG), bispectral index (BIS), respiration mechanics (RM) and impedance cardiography (ICG). BIS is intended for use on adult and pediatric patients. ICG monitoring is intended for use on adults only. The arrhythmia detection and ST Segment analysis are intended for adult patients. The monitors are additionally intended for use during patient transport inside hospitals. The monitors are not intended for MRI environments.	The monitor monitors parameters such as ECG (3-lead, 5-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO_2), Invasive or noninvasive blood pressure (dual-IBP, NIBP), Temperature (dual-TEMP), Expired CO_2. The monitor is equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both. The arrhythmia detection and ST Segment analysis are not intended for neonatal patients.	Similar
Intended patient population	adult, pediatric and neonatal patients	adult, pediatric and neonatal patients	Same
Intended application environment	Hospital environment.	Hospital environment.	Similar

ECG monitor			
Lead Mode	3-Lead: I, II, III 5-Leads: I, II, III, aVR, aVL, aVF, V 12-leads: I, II, III, aVR, aVL, aVF, V1 to V6	3-Lead: I, II, III 5-Leads: I, II, III, aVR, aVL, aVF, V 12-leads: I, II, III, aVR, aVL, aVF, V1 to V6	Same
Lead Naming Style	AHA, IEC	AHA, IEC	Same
Display Sensitivity	1.25mm/mV (×0.125), 2.5mm/mV (×0.25), 5mm/mV (×0.5), 10mm/mV (×1), 20mm/mV (×2), 40mm/mV (×4), AUTO gain	1.25 mm/mV (X0.125), 2.5 mm/mV (X0.25), 5 mm/mV (X0.5), 10 mm/mV (X1), 20 mm/mV (X2), 40 mm/mV (X4), Auto	Same
Sweep	6.25mm/s, 12.5mm/s, 25mm/s, 50mm/s	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s	Same
Measurement Range	Neonate: 15 to 350 bpm Pediatric: 15 to 350 bpm Adult: 15 to 300 bpm	Neonate: 15 to 350 bpm Pediatric: 15 to 350 bpm Adult: 15 to 300 bpm	Same
CMRR (Common Mode Rejection Ratio)	Diagnosis: >95dB Monitor: >105dB Surgery: >105dB	Diagnosis: >95dB (the Notch filter is off) Monitor: >105dB (the Notch filter is on) Surgery: >105dB (the Notch filter is on)	Similar
Accuracy	±1 bpm or ±1%, whichever is greater	±1 bpm or ±1%, whichever is greater	Same
Resolution	1 bpm	1 bpm	Same
Sensibility	200μV	200μV (lead II)	Same
Differential Input Impedance	>5MΩ	≥5 MΩ	Same
Leakage Current of Patient	<10μA	<10 μA	Same
ST value			
Measurement Range	-2.0 mV ~ +2.0 mV	-2.0 mV ~ +2.0 mV	Same
Accuracy	-0.8 mV to +0.8 mV: ±0.02 mV or 10%, whichever is greater. Beyond this range: not specified.	-0.8 to 0.8 mV: Beyond this range:±0.02 mV or ±10%, whichever is greater. Not specified.	Same
Pace			
Pulse Indicator	Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to2.0 ms Ascending time: 10 μs to 100 μs	Amplitude: ±2 to ±700 mV Width: 0.1 to 2 ms Rise time: 10 to 100 μs	Same
Pulse Rejection	Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to 2.0 ms Ascending time: 10 μs to 100 μs	Amplitude: ±2 to ±700 mV Width: 0.1 to 2 ms Rise time: 10 to 100 μs	Same

HR			
Measurement range	Neonate: 15 to 350 bpm Pediatric: 15 to 350 bpm Adult: 15 to 300 bpm	Neonate: 15 to 350 bpm Pediatric: 15 to 350 bpm Adult: 15 to 300 bpm	Same
Accuracy	±1% or 1 bpm, whichever is greater	±1 bpm or ±1%, whichever is greater	Same
Resolution	1 bpm	1 bpm	Same
RESP monitor			
Principle of Operation	Thoracic impedance	Trans-thoracic impedance	Same
Measurement Range	Adult: 0 to 120 rpm Pediatric/neonate: 0 rpm to 150rpm	Adult: 0 to 120 rpm Pediatric/neonate: 0 to 150 rpm	Same
Accuracy	Adult: 6 to 120 rpm: ±2 rpm, 0 to 5 rpm: not specified Pediatric/neonate: 6 to 150 rpm: ±2 rpm, 0 to 5 rpm: not specified	Adult: 6 to 120 rpm: ±2 rpm, 0 to 5 rpm: not specified Pediatric/neonate: 6 to 150 rpm: ±2 rpm, 0 to 5 rpm: not specified	Same
Resolution	1 rpm	1 rpm	Same
Waveform bandwidth	0.2Hz to 2.5Hz (-3dB)	0.2Hz to 2.5Hz (-3dB)	Same
Apnea Alarm	10s, 15s, 20s, 25s, 30s, 35s, 40s;	10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s	Same
NIBP monitor(EDAN Module)			
	oscillation	oscillation	Same
Measurement Range(mmHg)	Adult Systolic 40 to 270 mmHg Diastolic 10 to 215 mmHg Mean 20 to 235 mmHg Pediatric Systolic 40 to 230 mmHg Diastolic 10 to180 mmHg Mean 20 to 195 mmHg Neonate Systolic 40 to 135 mmHg Diastolic 10 to100 mmHg Mean 20 to 110 mmHg	Adult Systolic 40 to 270 mmHg Diastolic 10 to 215 mmHg Mean 20 to 235 mmHg Pediatric Systolic 40 to 200 mmHg Diastolic 10 to150 mmHg Mean 20 to 165 mmHg Neonate Systolic 40 to 135 mmHg Diastolic 10 to100 mmHg Mean 20 to 110 mmHg	Similar
Accuracy	Max mean error: ±5 mmHg, Max standard deviation: 8 mmHg	Max mean error: ±5 mmHg Max standard deviation: 8 mmHg	Same
Resolution	1mmHg	1mmHg	Same
Overpressure protection	Adult 297±3mmHg	297±3mmHg	Same
	Pediatric 245±3mmHg	240±3mmHg	Similar
	Pediatric 147±3mmHg	147±3mmHg	Same
Mode	Manual, Auto, Continuous	Manual, Auto, Continuous	Same
Measuring	1/2/3/4/5/10/15/30/60/90/120/240/480	1/2/3/4/5/10/15/30/60/90/120/240/48	Same

interval in AUTO Mode	min	0 min	
PR from NIBP			
Measurement range	40 bpm to 240bpm	40 to 240 bpm	Same
Accuracy	±3bpm or 3.5%, whichever is greater(EDAN);	±3bpm or 3.5%, whichever is greater	Same
SpO2 monitor(EDAN)			
Measurement Range	0-100%	0-100%	Same
Accuracy	70 to 100%: ±2% (measured without motion in adult/pediatric mode) 70 to 100%: ±3% (measured without motion in neonate mode) 0% to 69%: Not specified.	70 to 100%: ±2% (measured without motion in adult/pediatric mode) 70 to 100%: ±3% (measured without motion in neonate mode) 0% to 69%: Not specified.	Same
Resolution	1 %	1%	Same
PR			
Measurement Range	25 bpm to 300 bpm	25 bpm to 300 bpm	Same
Accuracy	±2bpm	±2bpm	Same
Resolution	1 bpm	1 bpm	Same
SpO2 monitor(Nellcor)			
Module	**Nellcor Module**	**Nellcor Module**	Same
Temperature monitor			
Technique	Thermal resistance	Thermal resistance	Same
Number of channels	2	2	Same
Measurement Range	0 to 50℃	0 to 50℃	Same
Accuracy	±0.1°C (±0.2 ºF)	±0.1°C (±0.2 ºF)	Same
Resolution	0.1°C	0.1℃	Same
C.O. Temperature			
Measurement method	Thermodilution method	Thermodilution method	Same
Measurement range	C.O.: 0.1 to 20L/min TB: 23 to 43℃ TI: -1 to 27℃	C.O.: 0.1 to 20L/min TB: 23 to 43℃ TI: -1 to 27℃	Same
Accuracy	C.O.: ±5% or ±0.2L/min, which is	C.O.: ±5% or ±0.1L/min, which is	Same

	greater TB,TI: ±0.1℃(without sensor)	greater TB,TI: ±0.1℃(without sensor)	
Resolution	C.O.: 0.1L/min TB,TI:0.1℃	C.O.: 0.1L/min TB,TI:0.1℃	Same
IBP monitor			
Technique	Direct invasive measurement	Direct invasive measurement	Same
Measurement Range	-50~300mmHg	-50~300mmHg	Same
Accuracy	±2% or ±1 mmHg, whichever is greater (without sensor)	±2% or ±1 mmHg, whichever is greater (without sensor)	Same
Resolution	1mmHg	1mmHg	Same
Transducer	5 (μV/V/mmHg) 200 to 3000 Ω	5 (μV/V/mmHg) 300 to 3000 Ω	Same
CO2 Monitor(Respironics)			
CO2 Module	Respironics CAPNOSTAT 5 LoFlo CO2(Sidestream)	Respironics CAPNOSTAT 5 LoFlo CO2(Sidestream)	Same
Measure Parameters	Respironics CAPNOSTAT 5 CO2（Mainstream CO2）	Respironics CAPNOSTAT 5 CO2（Mainstream CO2）	Same
AG Monitor（Phasein）			
Technique	Phasein AG	Phasein AG	Same
Justification of difference	Proposed devices and the predicate device use the same module, so has the same specification.		
Safety Classifications			
Type of protection against electric shock	Class I	Class I	Same
Ingress Protection	IPX1	IPX1	Same
The degree of RF	Group 1, Class A	Group 1, Class A	Same
The degree of protection against electric shock			
ECG, RESP, TEMP, IBP, C.O.	CF	CF	Same
ICG, NIBP, SpO_2,	BF	CF	Same
CO_2, AG, BIS, RM, ICG	BF	BF	Same
Electrical & Mechanical safety & Thermal safety Standards			
General Standards	IEC 60601-1:2005	IEC 60601-1:	Similar

		1988+A1:1991+A2:1995	
EMC Standards	IEC 60601-1-2:2007	IEC60601-1-2: 2001+A1:2004	
Alarm Standards	IEC 60601-1-8:2006	IEC60601-1-8:2003	
Biocompatibility Standards	ISO 10993-1:2009	ISO 10993-1:2003	
Software Standards	IEC 62304:2006	IEC 62304:2006	
Special Standards			
basic safety and essential performance for patient monitor	IEC 60601-2-49: 2011	IEC 60601-2-49: 2001	Similar
ECG	IEC 60601-2-27: 2011 IEC 60601-2-25: 2011	IEC 60601-2-27:2005 IEC 60601-2-25：1999 SP10	
NIBP	IEC 80601-2-30: 2009 ISO 81060-2	IEC60601-2-30:2000	
IBP	IEC 60601-2-34: 2011	IEC60601-2-34:2000	
AG, CO2	ISO 80601-2-55	ISO21647 :2004	
TEMP	ISO 80601-2-56 EN12470-4:2000	EN12470-4:2000	
Power supply			
AC power			
Requirement	100-240V, 50/60Hz	100-240V, 50/60 Hz	Same
Battery			
Rechargeable Battery	Yes	Yes	Same
Operation characteristic			
Installation and use	Portable Equipment Fix Equipment (when the system is installed on *Wall Mounting Bracket*)	Portable Equipment Fix Equipment (when the system is installed on *Wall Mounting Bracket*)	Same
Working System	Continuous operation	Continuous operation	Same
Physical Characteristics			
Weight	elite V5 : <6.2kg elite V6: <7.5kg elite V8: <14kg	<14kg	Similar
Dimensions	elite V5 : 333±2 mm (L) × 289±2 mm (H)× 211±2mm (W) elite V6: 384±2 mm (L) × 320±2 mm (H)× 213±2mm (W) elite V8: 425 mm (L) × 245 mm	425 mm (L) × 245 mm (W)× 382 mm (H)	

	(W)× 382 mm (H)		
LCD	elite V5: 12.1 inches LCD elite V6: 15 inches LCD elite V8: 17 inches LCD	17inch LCD	
LCD Resolution	elite V5: 800x600 elite V6: 1024*768 elite V8: 1280 *1024	1280×1024 pixels	
Environmental Specifications			
Temperature			
Working	+0°C to +40°C	+5°C to +40°C	Similar
Transport and Storage	-20°C to +55°C	-20°C to +55°C	
Humidity			
Working	15% to 95% (non-condensing)	25% ~ 80% (no coagulate)	Similar
Transport and Storage	15% to 95% (non-condensing)	25% ~ 93% (no coagulate)	Similar
Altitude			
Working	860hPa to 1060hPa	860hPa to 1060hPa	Same
Transport and Storage	700hPa to 1060hPa	700hPa to 1060hPa	
Other function			
Indicators			
Alarm indicator	3(red/yellow/blue)	3(red/yellow/blue)	Same
AC power indicator	1(green)	1(green)	Same
Battery indicator	1(green)	1(green/ yellow)	Same
Speaker	Yes	Yes	Same
Recorder	Yes	Yes	Same
Data Storage	Trend, NIBP Measurement Review, Alarm Review ,Arrhythmia Review, 12-Lead Diagnosis Review, Full-disclosure waveforms	Trend, NIBP Measurement Review, Alarm Review ,Arrhythmia Review, 12-Lead Diagnosis Review, Full-disclosure waveforms	Same
Interface	USB/VGA/Network/Nurse call/Defibrillator Synchronization/Analog Output/SD/PAM/DVI/RS232 port	USB/VGA/Network/Nurse call/Defibrillator Synchronization/Analog Output/SD/PAM/DVI/RS232 port	Same

Comparison to the predicate device BeneView T8

Item	Proposed device (elite V5, elite V6, elite V8)	Predicate device (BeneView T8)	Justification

K#	Current Submission	K092449	___
Intended use			
Description	The monitors are intended to be used for monitoring, storing, and reviewing of, and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates. The monitors are intended for use by trained healthcare professionals in hospital environments. The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO2), cardiac output (C.O.), anesthetic gas (AG), bispectral index (BIS), respiration mechanics (RM) and impedance cardiography (ICG). BIS is intended for use on adult and pediatric patients. ICG monitoring is intended for use on adults only. The arrhythmia detection and ST Segment analysis are intended for adult patients. The monitors are additionally intended for use during patient transport inside hospitals. The monitors are not intended for MRI environments.	This patient monitor is intended to be used for monitoring, displaying, reviewing, storing and transferring of multiple physiological parameters including ECG, heart rate (HR), respiration (Resp), temperature (Temp), SpO2, pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), cardiac output (C.O.), carbon dioxide (CO2), oxygen (O2), anesthetic gas (AG), impedance cardiograph (ICG), bispectral index (BIS) and respiration mechanics (RM) of single adult, pediatric and neonatal patients. Interpretation of resting 12-lead ECG and C.O. monitoring are restricted to adult patients only. The ICG is only for use on adult patients who meet the following requirements: height: 122 to 229 cm, weight: 30 to 159 kg. The arrhythmia detection, ST-segment, BIS and RM monitor are not intended for neonatal patients. This monitor is to be used in healthcare facilities by clinical professionals or under their direction. It is not intended for helicopter transport, hospital ambulance, or home use.	Similar
Intended patient population	adult, pediatric and neonatal patients	adult, pediatric and neonatal patients	Same

Intended application environment	Hospital environment.	It is not intended for helicopter transport, hospital ambulance, or home use.	Similar
ECG monitor			
Lead Mode	3-Lead: I, II, III 5-Leads: I, II, III, aVR, aVL, aVF, V 12-leads: I, II, III, aVR, aVL, aVF, V1 to V6	3-Lead: I, II, III 5-Leads: I, II, III, aVR, aVL, aVF, V 12-leads: I, II, III, aVR, aVL, aVF, V1 to V6	Same
Lead Naming Style	AHA, IEC	AHA, IEC	Same
Display Sensitivity	1.25mm/mV (×0.125), 2.5mm/mV (×0.25), 5mm/mV (×0.5), 10mm/mV (×1), 20mm/mV (×2), 40mm/mV (×4), AUTO gain	1.25 mm/mV (X0.125), 2.5 mm/mV (X0.25), 5 mm/mV (X0.5), 10 mm/mV (X1), 20 mm/mV (X2), 40 mm/mV (X4), Auto	Same
Sweep	6.25mm/s, 12.5mm/s, 25mm/s, 50mm/s	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s	Same
Measurement Range	Neonate: 15 to 350 bpm Pediatric: 15 to 350 bpm Adult: 15 to 300 bpm	Neonate: 15 to 350 bpm Pediatric: 15 to 350 bpm Adult: 15 to 300 bpm	Same
CMRR (Common Mode Rejection Ratio)	Diagnosis: >95dB Monitor: >105dB Surgery: >105dB	Diagnostic mode: ≥90 dB the Notch filter is off Monitor mode: ≥105 dB the Notch filter is off Surgical mode: ≥105 dB the Notch filter is off	Similar
Accuracy	±1 bpm or ±1%, whichever is greater	±1 bpm or ±1%, whichever is greater	Same
Resolution	1 bpm	1 bpm	Same
Sensibility	200μV	200μV (lead II)	Same
Differential Input Impedance	>5MΩ	≥5 MΩ	Same
Leakage Current of Patient	<10μA	<10 μA	Same
ST value			
Measurement Range	-2.0 mV ~ +2.0 mV	-2.0 mV ~ +2.0 mV	Same
Accuracy	-0.8 mV to +0.8 mV: ±0.02 mV or 10%, whichever is greater. Beyond this range: not specified.	-0.8 to 0.8 mV: Beyond this range:±0.02 mV or ±10%, whichever is greater. Not	Same

			specified.	
Pace				
Pulse Indicator	Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to2.0 ms Ascending time: 10 μs to 100 μs		Amplitude: ±2 to ±700 mV Width: 0.1 to 2 ms Rise time: 10 to 100 μs	Same
Pulse Rejection	Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to 2.0 ms Ascending time: 10 μs to 100 μs		Amplitude: ±2 to ±700 mV Width: 0.1 to 2 ms Rise time: 10 to 100 μs	Same
HR				
Measurement range	Neonate: 15 to 350 bpm Pediatric: 15 to 350 bpm Adult: 15 to 300 bpm		Neonate: 15 to 350 bpm Pediatric: 15 to 350 bpm Adult: 15 to 300 bpm	Same
Accuracy	±1% or 1 bpm, whichever is greater		±1 bpm or ±1%, whichever is greater	Same
Resolution	1 bpm		1 bpm	Same
RESP monitor				
Principle of Operation	Thoracic impedance		Trans-thoracic impedance	Same
Measurement Range	Adult: 0 to 120 rpm Pediatric/neonate: 0 rpm to 150rpm		Adult: 0 to 120 rpm Pediatric/neonate: 0 to 150 rpm	Same
Accuracy	Adult: 6 to 120 rpm: ±2 rpm, 0 to 5 rpm: not specified Pediatric/neonate: 6 to 150 rpm: ±2 rpm, 0 to 5 rpm: not specified		7 to 150 rpm: ±2 rpm or ±2%, whichever is greater 0 to 6 rpm: Not specified.	Similar
Resolution	1 rpm		1 rpm	Same
Waveform bandwidth	0.2Hz to 2.5Hz (-3dB)		0.2 to 2 Hz (-3 dB)	Similar
Apnea Alarm	10s, 15s, 20s, 25s, 30s, 35s, 40s;		10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s	Same
NIBP monitor				
Principle of Operation	oscillation（EDAN, M3600, SunTech NIBP）		oscillation	Same
Measurement Range(mmHg)	Adult			Similar
	Systolic	EDAN NIBP	40 mmHg to 270 mmHg	40 to 270
		M3600	60 mmHg to 250 mmHg	
		SunTech NIBP	60 mmHg ~ 250 mmHg	
	Diastol	EDAN NIBP	10 mmHg	10 to 210

	ic		to 215 mmHg		
		M3600	40 mmHg to 200 mmHg		
		SunTech NIBP	30 mmHg ~ 190 mmHg		
	Mean	EDAN NIBP	20 mmHg to 235 mmHg	20 to 230	
		M3600	45 mmHg to 235 mmHg		
		SunTech NIBP	40 mmHg ~ 210 mmHg		
	Pediatric				
	Systolic	EDAN NIBP	40 mmHg to 230 mmHg	40 to 200	
		M3600	60 mmHg to 250 mmHg		
		SunTech NIBP	40 mmHg ~ 230 mmHg		
	Diastolic	EDAN NIBP	10 mmHg to 180 mmHg	10 to 150	
		M3600	40 mmHg to 200 mmHg		
		SunTech NIBP	20 mmHg ~ 160 mmHg		
	Mean	EDAN NIBP	20 mmHg to 195 mmHg	20 to 165	
		M3600	45 mmHg to 235 mmHg		
		SunTech NIBP	30 mmHg ~ 175 mmHg		
	Neonate				
	Systolic	EDAN NIBP	40 mmHg to 135 mmHg	40 to 135	
		M3600	40 mmHg to		

			120 mmHg		
		SunTech NIBP	40 mmHg ~ 130 mmHg		
	Diastolic	EDAN NIBP	10 mmHg to 100 mmHg	10 to 100	
		M3600	20 mmHg to 90 mmHg		
		SunTech NIBP	20 mmHg ~ 90 mmHg		
	Mean	EDAN NIBP	20 mmHg to 110 mmHg	20 to 110	
		M3600	30 mmHg to 100 mmHg		
		SunTech NIBP	30 mmHg ~ 100 mmHg		
Accuracy	Max mean error: ±5 mmHg,Max standard deviation: 8 mmHg(EDAN,M3600, SunTech);			Max mean error: ±5 mmHg Max standard deviation: 8 mmHg	Same
Resolution	1mmHg(EDAN,M3600, SunTech);			1mmHg	Same
Overpressure protection	Adult	297±3mmHg(EDAN) <300mmHg(M3600, SunTech)		297±3mmHg	Similar
	Pediatric	245±3mmHg(EDAN) <300mmHg(M3600, SunTech)		240±3mmHg	
	Pediatric	147±3mmHg(EDAN) <150mmHg(M3600, SunTech)		147±3mmHg	
Mode	Manual, Auto, Continuous			Manual, Auto and STAT	Similar
Measuring interval in AUTO Mode	1/2/3/4/5/10/15/30/60/90/120/240/480 min(EDAN) 1/2/3/4/5/10/15/30/60/90 min, 2/4/8h(M3600) 1/2/3/4/5/10/15/30/60/90/120/240/480 min(SunTech)			1, 2, 2.5, 3, 5, 10, 15, 20, 30, 60, 90, 120, 180, 240 or 480 min	Similar
PR from NIBP					
Measurement range	40 bpm to 240bpm(EDAN); Adult/ Pediatric mode: 40bpm to 200bpm,Neonatal mode: 40 bpm to 240bpm (M3600); 30 bpm ~220bpm(SunTech)			40 to 240 bpm	Similar
Accuracy	±3bpm or 3.5%, whichever is greater(EDAN);			±3bpm or ±3%, whichever is greater	Similar

	± 2 bpm or 2% of the readings(M3600); ±3bpm or ±2%, whichever is greater(SunTech);		
SpO2 monitor(EDAN)			
Measurement Range	0-100%	0-100%	Same
Accuracy	70 to 100%: ±2% (measured without motion in adult/pediatric mode) 70 to 100%: ±3% (measured without motion in neonate mode) 0% to 69%: Not specified.	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) 0% to 69%: Not specified.	Same
Resolution	1 %	1%	Same
PR			
Measurement Range	25 bpm to 300 bpm	20 to 254 bpm	Similar
Accuracy	±2bpm	±3 bpm (measured without motion) ±5 bpm (measured with motion)	Similar
Resolution	1 bpm	1 bpm	Same
SpO2 monitor(Nellcor)			
Module	**Nellcor Module**	**Nellcor Module**	Same
Temperature monitor			
Technique	Thermal resistance	Thermal resistance	Same
Number of channels	2	2	Same
Measurement Range	0 to 50℃	0 to 50℃	Same
Accuracy	±0.1°C (±0.2 ºF)	±0.1 °C or ±0.2 °F (without probe)	Same
Resolution	0.1°C	0.1℃	Same
C.O. Temperature			
Measurement method	Thermodilution method	Thermodilution method	Same
Measurement range	C.O.: 0.1 to 20L/min TB: 23 to 43℃ TI: -1 to 27℃	C.O.: 0.1 to 20L/min TB: 23 to 43℃ TI: 0 to 27℃	Similar

Accuracy	C.O.: ±5% or ±0.2L/min, which is greater TB,TI: ±0.1℃(without sensor)	C.O.: ±5% or ±0.1L/min, which is greater TB,TI: ±0.1℃(without sensor)	Same
Resolution	C.O.: 0.1L/min TB,TI:0.1℃	C.O.: 0.1L/min TB,TI:0.1℃	Same
IBP monitor			
Technique	Direct invasive measurement	Direct invasive measurement	Same
Measurement Range	-50~300mmHg	-50~300mmHg	Same
Accuracy	±2% or ±1 mmHg, whichever is greater (without sensor)	±2% or ±1 mmHg, whichever is greater (without sensor)	Same
Resolution	1mmHg	1mmHg	Same
Transducer	5 (μV/V/mmHg) 200 to 3000 Ω	5 (μV/V/mmHg) 300 to 3000 Ω	Same
CO2 Monitor(EDAD CO2 Module(Sidestream), Respironics CAPNOSTAT 5 LoFlo CO2(Sidestream))			
Technique	Infra-red Absorption Technique	Infra-red Absorption Technique	Same
Measure Parameters	$EtCO_2$, $FiCO_2$, AwRR	$EtCO_2$, $FiCO_2$, AwRR	Same
CO_2 Measurement range	0 mmHg to 150 mmHg	0 to 99 mmHg	Similar
AwRR Measurement range	2 rpm to 150 rpm	0 to 150 rpm	Similar
Accuracy	EDAN: Respiratory rate ≤60rpm: ± 2mmHg, 0mmHg to 40mmHg, ± 5% of reading, 41mmHg to 70mmHg, ± 8% of reading, 71mmHg to 100mmHg, ± 10% of reading, 101mmHg to 150mmHg, Respiratory rate >60rpm: ±12% or ± 4mmHg of reading, whichever is greater **Respironics:** ± 2 mmHg, 0 to 40 mmHg, ± 5 % of reading, 41 to 70 mmHg, ± 8 % of reading, 71 to 100 mmHg, ± 10 % of reading, 101 to 150 mmHg, ± 12% of reading, RR is over 80 rpm	0 to 38 mmHg: ±2 mmHg 39 to 99 mmHg: ±5% of the reading+0.08% of (the reading-38)	Similar

Resolution	1 mmHg				1 mmHg			Same
Sample flow rate	EDAN:70ml/min or 100ml/min, optional (±15ml/min) **Respironics:**50 ±10 ml/min				$50^{-7.5}_{+15}$ ml/min			Similar
Apnea Alarm Delay	10s, 15s, 20s, 25s, 30s, 35s, 40s;				10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s			Same
CO2 Monitor （Respironics CAPNOSTAT 5 CO2（Mainstream CO2）								
Measure Parameters	$EtCO_2$, $FiCO_2$, AwRR				$EtCO_2$, $FiCO_2$, AwRR			Same
CO_2 Measurement range	0 mmHg to 150 mmHg				0 to 150 mmHg			Same
AwRR measurement range	0 rpm to 150 rpm				0 to 150 rpm			Same
Accuracy	± 2 mmHg, 0 to 40 mmHg, ± 5 % of reading, 41 to 70 mmHg, ± 8 % of reading, 71 to 100 mmHg, ± 10 % of reading, 101 to 150 mmHg				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			Similar
Resolution	1 mmHg				1 mmHg			Same
awRR measurement accuracy	± 1 rpm				1 rpm			Same
AG Monitor（Phasein and Drager）								
Technique	Infrared absorption				Infrared absorption			Same
Warm-up time	Full accuracy mode: < 20s(Phasein) Full accuracy mode：< 450 s(Drager)				Full accuracy mode: 10 min			Similar
Sample flow rate	50±10ml/min(Phasein) 200 mL/min ±20 mL/min(Drager)				Adult, pediatric: 120, 150, 200 ml/min Neonate: 70, 90, 120 ml/min Accuracy: ±10 ml/min or ±10%, whichever is greater			Similar
Measurement Range and Accuracy	Phasein			Range (%REL)	Accuracy (%ABS)	Range (%REL)	Accuracy (%ABS)	Similar
	CO	Phasein	Sidest	0 to 15 vol%	±(0.2 vol% + 2% of	0 to 1 1 to 5	±0.1 ±0.2	Similar

	2		rea m	15 to 25 vol%	reading) Unspecified	5 to 7 7 to 10 >10	±0.3 ±0.5 Not specified	
			Ma ins tre am	0 to 10 vol% 10 to 15vol% 15 to 25 vol%	±(0.2 vol% + 2% of reading) ±(0.3 vol% + 2% of reading) Unspecified			
		Drager		0 to 13.6 Vol%	±(0.43 Vol% + 8 % rel.)			
	O 2	Phasein(S idestream)		0 to 100 vol %	±(1 vol% + 2% of reading)	0 to 25 25 to 80 80 to 100	±1 ±2 ±3	
		Drager		0 to 100 Vol%	±(2.5 Vol% + 2.5 % rel.)			
	N_2O	Phasein (Sidestrea m &Mainstr eam)		0 to 100 vol%	±(2 vol% + 2% of reading)	0 to 20 20 to 100	±2 ±3	
		Drager		0 to 100 Vol%	±(2 Vol% + 8 % rel.)			
	D es	Phasein(S idestream &Mainstr eam)		0 to 22 vol % 22 to 25 vol %	±(0.15 vol% + 5% of reading) Unspecified	0 to 1 1 to 5 5 to 10 10 to 15 15 to 18 >18	±0.15 ±0.2 ±0.4 ±0.6 ±1 Not specified	
		Drager		0 to 20 Vol%	±(0.2 Vol% + 15 % rel.)			
	S ev	Phasein （Sidestr eam &Mainstr eam）		0 to 10 vol % 10 to 25 vol %	±(0.15 vol% + 5% of reading) Unspecified	0 to 1 1 to 5 5 to 8 >8	±0.15 ±0.2 ±0.4 Not specified	
		Drager		0 to 10 Vol%	±(0.2 Vol% + 15 % rel.)			
	E nf	Phasein （Sidestr eam &Mainstr eam）		0 to 8 vol % 8 to 25 vol %	±(0.15 vol% + 5% of reading) Unspecified	0 to 1 1 to 5 >5	±0.15 ±0.2 Not specified	
		Drager		0 to 10	±(0.2 Vol% +			

			Vol%	15 % rel.)			
	Iso	Phasein （Sidestream &Mainstream）	0 to 8 vol % 8 to 25 vol %	±(0.15 vol% + 5% of reading) Unspecified	0 to 1 1 to 5 >5	±0.15 ±0.2 Not specified	
		Drager	0 to 8.5 Vol%	±(0.2 Vol% + 15 % rel.)			
	Hal	Phasein （Sidestream &Mainstream）	0 to 8 vol % 8 to 25 vol %	±(0.15 vol% + 5% of reading) Unspecified	0 to 1 1 to 5 >5	±0.15 ±0.2 Not specified	
		Drager	0 to 8.5 Vol%	±(0.2 Vol% + 15 % rel.)			

ICG			
Technique	Thoracic electrical bioimpedance	Thoracic electrical bioimpedance (TEB)	Same
Measurement range	SV: 0 ml/beat～250 ml/beat HR: 40 bpm～250bpm C.O.: 0 L/min～30 L/min	SV: 5 to 250 ml/beat HR: 44 to 185 bpm C.O.: 1.4 to 15 L/min	Similar
Accuracy	SV: Undefined HR: ±2bpm C.O.: Undefined	SV: Not specified. HR: ±2 bpm C.O.: Not specified.	Same
BIS			
Technique	Bispectral index	Bispectral index	Same
Measured parameters	EEG BIS: 0 to 100	EEG BIS: 0 to 100	Same
Impedance range	0 to 999 kΩ	0 to 999 kΩ	Same
Sweep speed	6.25mm/s, 12.5mm/s, 25mm/s, 50mm/s	6.25 mm/s, 12.5 mm/s, 25 mm/s or 50 mm/s	Same
Noise (EEG Waveform)	<0.3μV (0.25Hz～50Hz)	<0.3μV (0.25Hz～50Hz)	Same
EEG bandwidth	0.25Hz～50Hz	0.25 to 100 Hz	Same
RM			
Frequency response	>10Hz	≥30 Hz	Similar
Flow			

Measurement range	Adult: 2.0 L/min to 180 L/min Pediatric: 0.75 L/min to 100 L/min Neonatal: 0.25 L/min to 30 L/min	Adult/pediatric*: ± (2 to 120) L/min Infant: ± (0.5 to 30) L/min	Similar
Accuracy	Adult: 0.5 L/min or ± 3% of reading, whichever is greater Pediatric: 0.25 L/min or ± 3% of reading, whichever is greater Neonatal: 0.125 L/min or ± 3% of reading, whichever is greater	Adult/pediatric*: 1.5 L/min or ±10% of the reading, whichever is greater Infant: 0.5 L/min or ±10% of the reading, whichever is greater	
Resolution	1.0 L/min	0.1 L/min	
Paw(or Airway Pressure)			
Measurement range	-120 cmH_2O to 120 cmH_2O	-20 to 120 cmH_2O	Similar
Accuracy	0.5 cmH_2O or ± 2% of reading, whichever is greater	±3%	
Resolution	1 cmH_2O	0.1 cmH_2O	
MVe/MVi			
Measurement range	Adult: 1 L/min to 30.00 L/min Pediatric: 0.3 L/min to 20 L/min Neonatal: 0.1 L/min to 3 L/min	Adult/Pediatric*: 2 to 60 L/min Infant: 0.5 to 15 L/min	Similar
Accuracy	Adult: 0.1 L/min Pediatric: 0.1 L/min Neonatal: 0.1 L/min	±10%×reading	
TVe/TVi			
Measurement range	Adult: 40 mL to 2500 mL Pediatric: 6 mL to 750 mL Neonatal: 2 mL to 100 mL	Adult/Pediatric*: 100 to 1500 ml Infant: 20 to 500 ml	Similar
Resolution	1.0 mL	1 ml	
Accuracy	Adult: ± 10.0 mL or ± 5% of reading, whichever is greater Pediatric: ± 3.0 mL or ± 5% of reading, whichever is greater Neonatal: ± 1.0 mL or ± 5% of reading, whichever is greater	Adult/pediatric*: ±10% or 15 ml, whichever is greater Infant: ±10% or 6 ml, whichever is greater	
RR (RM)			
Measurement range	2 rpm to 150 rpm	4 to 120 rpm	Similar
Accuracy	± 1 rpm	4 to 99 rpm ±1 rpm 100 to 120 rpm ±2 rpm	
Safety Classifications			

Type of protection against electric shock	Class I	Class I	Same
Ingress Protection	IPX1	IPX1	Same
The degree of RF	Group 1, Class A	Group 1, Class A	Same
The degree of protection against electric shock			
ECG, RESP, TEMP, IBP, C.O.	CF	CF	Same
ICG, NIBP, SpO_2,	BF	CF	Similar
CO_2, AG, BIS, RM, ICG	BF	BF	Same
Electrical & Mechanical safety & Thermal safety Standards			
General Standards	IEC 60601-1:2005	IEC 60601-1: 1988+A1:1991+A2:1995	Similar
EMC Standards	IEC 60601-1-2:2007	IEC60601-1-2: 2001+A1:2004	
Alarm Standards	IEC 60601-1-8:2006	IEC60601-1-8:2003	
Biocompatibility Standards	ISO 10993-1:2009	ISO 10993-1:2003	
Software Standards	IEC 62304:2006	IEC 62304:2006	
Special Standards			
basic safety and essential performance for patient monitor	IEC 60601-2-49: 2011	IEC 60601-2-49: 2001	Similar
ECG	IEC 60601-2-27: 2011 IEC 60601-2-25: 2011	IEC 60601-2-27:2005 IEC 60601-2-25：1999	
NIBP	IEC 80601-2-30: 2009 ISO 81060-2	IEC60601-2-30:2000	
IBP	IEC 60601-2-34: 2011	IEC60601-2-34:2000	
AG, CO2, RM	ISO 80601-2-55	ISO21647 :2004	
TEMP	ISO 80601-2-56 EN12470-4:2000	EN12470-4:2000	
Power supply			

AC power			
Requirement	100-240V, 50/60Hz	100-240V, 50/60 Hz	Same
Battery			
Rechargeable Battery	Yes	Yes	Same
Operation characteristic			
Installation and use	Portable Equipment Fix Equipment (when the system is installed on *Wall Mounting Bracket*)	Portable Equipment Fix Equipment (when the system is installed on *Wall Mounting Bracket*)	Same
Working System	Continuous operation	Continuous operation	Same
Physical Characteristics			
Weight	elite V5 : <6.2kg elite V6: <7.5kg elite V8: <14kg	<14.5 kg	Similar
Dimensions	elite V5 : 333±2 mm (L) × 289±2 mm (H)× 211±2mm (W) elite V6: 384±2 mm (L) × 320±2 mm (H)× 213±2mm (W) elite V8: 425 mm (L) × 245 mm (W)× 382 mm (H)	400×370×193 mm	
LCD	elite V5: 12.1 inches LCD elite V6: 15 inches LCD elite V8: 17 inches LCD	17inch LCD	
LCD Resolution	elite V5: 800x600 elite V6: 1024*768 elite V8: 1280 *1024	1280×1024 pixels	
Environmental Specifications			
Temperature			
Working	+0°C to +40°C	5 to 40	Similar
Transport and Storage	-20°C to +55°C	20 to 60	
Humidity			
Working	15% to 95% (non-condensing)	15% to 95% (non-condensing)	Same
Transport and Storage	15% to 95% (non-condensing)	10% to 95%(non-condensing)	Similar
Altitude			
Working	860hPa to 1060hPa	425 to 809mmHg	Similar
Transport and	700hPa to 1060hPa	120 to 809mmHg	

Storage			
Other function			
Indicators			
Alarm indicator	3(red/yellow/blue)	3(red/yellow/blue)	Same
AC power indicator	1(green)	1(green)	Same
Battery indicator	1(green)	1(green/ yellow)	Same
Speaker	Yes	Yes	Same
Recorder	Yes	Yes	Same
Data Storage	Trend, NIBP Measurement Review, Alarm Review ,Arrhythmia Review, 12-Lead Diagnosis Review, Full-disclosure waveforms	Trends, Parameter alarms, Arrh. events, NIBP measurements, Interpretation of resting 12-lead ECG results, Full-disclosure waveforms	Similar
Interface	USB/VGA/Network/Nurse call/Defibrillator Synchronization/Analog Output/SD/PAM/DVI/RS232 port	USB/Network/Nurse call/Micro-Dt/Network/CIS/SM R/CF/DVI port	Similar

Comparison to the predicate iM70

Item	**Proposed devices elite V5, elite V6, elite V8**	**Predicate device iM70**	**Justification**
K#	Current Submission	K131971	____
RESP			
Patient	Adult pediatric neonate	Adult pediatric neonate	Same
Method	Impedance between RA-LL, RA-LA	Impedance between RA-LL, RA-LA	Same
Measurement lead	Options are lead I and II. The default is lead II.	Options are lead I and II. The default is lead II.	Same
Calculation Type	Manual, Automatic	Manual, Automatic	Same
Baseline Impedance Range	200 Ω to 2500 Ω (with ECG cables of 1 K Ω resistance)	200 Ω to 2500 Ω (with ECG cables of 1 K Ω resistance)	Same
Measuring Sensitivity	Within the baseline impedance range: 0.3 Ω	Within the baseline impedance range: 0.3 Ω	Same

Waveform Bandwidth	0.2 Hz to 2.5 Hz (-3 dB)	0.2 Hz to 2.5 Hz (-3 dB)	Same
Respiration Excitation Waveform	Sinusoid, 62.8 kHz(± 10%), <500 μA	Sinusoid, 62.8 kHz(± 10%), <500 μA	Same
RR Measuring Range			
Adult	0 rpm to120 rpm	0 rpm to120 rpm	Same
Neo/Ped	0 rpm to150 rpm	0 rpm to150 rpm	Same
Resolution	1 rpm	1 rpm	Same
Accuracy			
Adult	6 to 120 rpm: ±2 rpm 0 to 5 rpm: not specified	6 to 120 rpm: ±2 rpm 0 to 5 rpm: not specified	Same
Neo/Ped	6 to 150 rpm: ±2 rpm 0 to 5 rpm: not specified	6 to 150 rpm: ±2 rpm 0 to 5 rpm: not specified	Same
Gain Selection	x0.25, x0.5, x1, x2, x3, x4, x5	x0.25, x0.5, x1, x2, x3, x4, x5	Same
Sweep	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s	Same
Apnea Alarm Time Setup	10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s; default value is 20 s.	10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s; default value is 20 s.	Same
WI-FI			
IEEE	802.11b/g/n	802.11b/g/n	Same
Frequency Band	2.4GHz ISM band	2.4GHz ISM band	Same
Modulation	OFDM with BPSK, QPSK, 16-QAM, and 64-QAM 802.11b with CCK and DSSS	OFDM with BPSK, QPSK, 16-QAM, and 64-QAM 802.11b with CCK and DSSS	Same
Typical Transmit Power (±2 dBm)	17 dBm for 802.11b DSSS 17 dBm for 802.11b CCK 15 dBm for 802.11g/n OFDM	17 dBm for 802.11b DSSS 17 dBm for 802.11b CCK 15 dBm for 802.11g/n OFDM	Same

Care and Cleaning			
Recommended cleaning agents	Mild neutral detergent Ethanol (75%) Isopropanol (70%)	Mild neutral detergent Ethanol (75%) Isopropanol (70%)	Same
Recommended types of disinfecting agents	Ethanol (75%) Isopropanol (70%) Cidex OPA (High level disinfection of intracavitary temperature probe only)	Ethanol (75%) Isopropanol (70%) Cidex OPA (High level disinfection of intracavitary temperature probe only)	Same
Cleaning	surface-clean the monitor with a soft cloth dampened with the cleaning solution	surface-clean the monitor with a soft cloth dampened with the cleaning solution	Same
Disinfecting	Following hospital's policy	Following hospital's policy	Same

All the differences don't affect the safety and effectiveness which is concluded after all the required testing, so no safety and effectiveness issues relating to the patient monitor come into conclusion.

10. Performance Data:

Non-clinical data:

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the elite V5, elite V6 and elite V8 Patient Monitor were conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The worst case of the whole system is considered tissue contacting for a duration of less than 24 hours. And the battery of testing included the following tests:

- Cytotoxicity
- Skin Sensitization
- Skin Irritation

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the elite V5, elite V6 and elite V8 Patient Monitor device, consisting of all the modules and accessories in the system. The system complies with the IEC 60601-1:2005/A1: 2012, IEC 60601-1-8: 2006, IEC 60601-2-25: 2011, IEC 60601-2-27: 2011, ANSI/AAMI EC57: 2012, IEC 80601-2-30: 2009, IEC 60601-2-34: 2011 , IEC 60601-2-49: 2011, ISO 80601-2-55: 2011, ISO

80601-2-56: 2009, ISO 80601-2-61: 2011 and ISO 81060-2: 2013 standards for safety and the IEC 60601-1-2:2007 standard for EMC.

standards	conclusion
IEC60601-1-8 - 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- Test report of elite V series (2006).	Pass
IEC 60601-2-25 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs - Test Report of elite V series (2011）	Pass
• IEC 60601-2-27 Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment - Test Report of elite V series（2011）	Pass
IEC 60601-2-34 - Medical electrical equipment - Part 2-34: Particular requirements for the basic safety, including essential performance, of invasive blood pressure monitoring equipment - Test Report of elite V series（2011	Pass
IEC60601-2-49 - Medical electrical equipment Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment - Test Report of elite V series(2011) – (This standard is not recognized by FDA)	Pass
IEC 80601-2-30 - Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers - Test Report of elite V series	Pass
ISO 80601-2-55 - Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors - Test Report of elite V series	Pass
ISO 80601-2-56 - Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement - Test Report of elite V series.	Pass
ISO 80601-2-61 - Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment - Test Report of elite V series	Pass
IEC62366 - Medical devices - Application of usability engineering to	Pass

medical devices - Test Report of elite V Series	

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Clinical data:

Not applicable.

Summary

Based on the non-clinical and clinical performance as documented in the system development, the subject devices were found to have a safety and effectiveness profile that is similar to the predicate device.

11. Conclusion

The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that the elite V5, elite V6 and elite V8 Patient Monitor device should perform as intended in the specified use conditions. The clinical data demonstrate that the subject devices perform comparably to the predicate device that is currently marketed for the same intended use. In other words, the subject the elite V5, elite V6 and elite V8 Patient Monitor devices are substantially equivalent to the predicate devices.