



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 29, 2016

Edan Instruments, Inc.
% Doug Worth
Sr. Dir. US RA/QA
Edan Medical
1200 Crossman Ave. Suite 200
Sunnyvale, California 94086

Re: K152552

Trade/Device Name: Patient Monitor, model iM20

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, MLD, DRT, DXN, DSK, FLL, DQA, CCK, GXY, DPS, DRG

Dated: March 22, 2016

Received: March 28, 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a large, light gray watermark of the FDA logo.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K152552

Device Name
Patient Monitor, model iM20

Indications for Use (Describe)

iM20 Patient Monitor (hereinafter called monitor) is 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), and invasive blood pressure (IBP), and carbon dioxide (CO2).

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

The monitor is additionally intended for use during patient transport inside and outside of the hospital environment.

The monitor is not intended for airplane, helicopter transport, home use and 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
3/F - B, Nanshan Medical
Equipments Park, Nanhai Rd 1019#,
Shekou, Nanshan Shenzhen,
518067 P.R. China
Tel: +86(0755) 26858736
Fax: +1 (408) 418-4059

Contact person:

Queena Chen

Preparing date:

March 22, 2015

**2. Device name and
classification:**

Device Name: Patient Monitor

Model: iM20

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 cardiometer 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

882.1320 Cutaneous electrode/GXY

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) Philips Medizin.Systeme Boeblingen GmbH IntelliVue MP2
cleared under K102562.
- 2) Edan Instruments, Inc. iM70/ K131971

5. Reason for Submission

Introduce new device iM20

6. Pre-Submission, IDE

Not applicable, there is no prior submission.

7. Device Description:

The iM20 Patient Monitor System (hereinafter called iM20) can perform long-time continuous monitoring of multiple physiological parameters, including ECG, respiration (RESP), non-invasive blood pressure (NIBP), oxygen saturation of the blood (SpO₂), pulse rate (PR), temperature (TEMP), invasive pressure (IBP), Carbon Dioxide (CO₂). The system capabilities include storing, displaying, analyzing and controlling such data afterwards. When necessary, alarms will be produced so that doctors and nurses can manage patient care appropriately. The system is intended to be used during patient transport inside and outside of the hospital environment.

iM20 can be utilized in two ways, as an independent monitor and as a module of V series Patient Monitor (including models elite V5, elite V6 and elite V8). When used as an independent monitor, it can simultaneously monitor, store, review several parameters data. And transfer patient data to V series patient monitor only under the transport mode. As a highly portable monitor, its compact design makes it particularly appropriate inside hospital and vehicle ambulance transport environments. When as a multi-measurement module, when the iM20 is directly connected to a V series patient monitor, it can provide the measurements, trends, and patient information. When connected, the V series Patient Monitor controls the connected iM20, including all alarm functionality. So no alarms are available on iM20 in such application and iM20 takes power from the V series Patient Monitor.

8. Intended Use/Indications for Use:

iM20 Patient Monitor (hereinafter called monitor) is 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), and invasive blood pressure (IBP), and carbon dioxide (CO₂).

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

The monitor is additionally intended for use during patient transport inside and outside of the hospital environment.

The monitor is not intended for airplane, helicopter transport, home use and 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, detailed substantial equivalence discussion are included in the following tables.

Comparison to Primary Predicate Device MP2

Item	Proposed device: iM20	Predicate device: IntelliVue MP2	Comparison Result
510(k) Number	Current Submission	K102562	
Indications for Use			
Intended Use	<p>iM20 Patient Monitor is 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 to be used by trained healthcare professionals in a hospital environment.</p> <p>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), and carbon dioxide (CO₂).</p> <p>The arrhythmia detection and ST-segment monitoring are intended for adult only. Neonatal and pediatric</p>	<p>Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. Intended for monitoring, recording of, and to generate alarms for multiple physiological parameters of adults, pediatrics and neonates in hospital environments. The</p>	Different

	<p>patients are not clinically validated.</p> <p>The monitors are indicated for use by health care professionals or under their direction whenever there is a need for monitoring the physiological parameters of patients.</p> <p>The monitors are additionally intended for use during patient transport inside and outside of the hospital environment. The monitor is not intended for airplane, helicopter transport, home use or MRI environments.</p>	<p>MP2, X2, MP5, MP5T, MP20, MP30, MP40, and MP50 are additionally intended for use in transport situations within hospital environments. The MP2, X2 and MP5 are also intended for use during patient transport outside of a hospital environment.</p>	
ECG Function			
HR Calculation			
Range	ADU: 15 bpm to 300 bpm PED/NEO: 15 bpm to 350 bpm	Adult/pedi: 15 to 300 bpm Neo range: 15 to 350 bpm	Different
Accuracy	±1% or 1 bpm, whichever is greater	±1 % of range	Different
Resolution	1 bpm	1bpm	Same
Sensitivity	≥300 μVPP	≥200 μVpeak	Different
PVC Rate			
Range	ADU: 0 to 300 PVCs/ min PED/NEO: 0 to 350 PVCs/ min	0 to 300 bpm	Different
Resolution	1 PVCs/min	1 bpm	Different
ST Numeric			
Range	-2.0 mV to +2.0 mV	-20 to +20 mm	Different
Accuracy	-0.8 mV to +0.8 mV: ±0.02 mV or 10%, which ever one is greater. Beyond this range: not specified.	±0.5mm or 15%, which ever one is greater	Different
Resolution	0.01 mV	0.1mm	Different
Range of Sinus and SV Rhythm			
Brady	Adult: RR interval for 5 consecutive QRS complex ≥ 1.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex ≥ 1 s.	Adult: 15 to 60 bpm Pedi: 15 to 80 bpm Neo: 15 to 90 bpm	Different
Normal	Adult: 0.5s < RR interval for 5 consecutive QRS complex < 1.5 s. Pediatric/neonatal: 0.375s < RR interval	Adult: 60 to 100 bpm Pedi: 80 to 160	Different

	for 5 consecutive QRS complex < 1 s.	bpm Neo: 90 to 180 bpm	
Tachy	Adult: RR interval for 5 consecutive QRS complex ≤ 0.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex ≤ 0.375 s.	Adult: >100 bpm Pedi: >160 bpm Neo: >180 bpm	Different
Bandwidth (-3dB)	Diagnosis: 0.05Hz to 150Hz Monitor: 0.5Hz to 40Hz Surgery: 1Hz to 20Hz	Diagnosis: Adult/neo/pedi: 0.05 to 150 Hz Monitor: Adult: 0.5 to 40 Hz Neo/pedi: 0.5 to 55 Hz Filter Mode: Adult/neo/pedi: 0.5 to 20 Hz	Different
CMRR (Common Mode Rejection Ratio)	Diagnosis: >95dB (the Notch filter is off) Monitor: >105dB (the Notch filter is on) Surgery: >105dB (the Notch filter is on)	Diagnostic mode: >86 dB (with a 51 k Ω /47 nF imbalance). Filter mode: >106 dB (with a 51 k/47 nF imbalance).	Different
Differential Input Impedance	>5M Ω	>2 M Ω RA-LL leads (Resp) >5 M Ω at all other leads (at 10 Hz including patient cable)	Different
Input Signal Range	± 10 mVPP	± 5 mV (peak-to-peak value)	Different
Electrode Offset Potential Tolerance	± 500 mV	± 500 mV	Same
Auxiliary Current (Leads off detection)	Active electrode: <100nA Reference electrode: <900nA	Active electrode: <100nA Reference electrode: <900nA	Same
Pace			
Pulse Indicator	Pulse is marked if the requirements of IEC 60601-2-27: 2011, Sect. 201.12.1.101.12 are met:	± 2 mV to ± 700 mV and widths from 0.1 ms to 2.0 ms	Different

	Amplitude: ± 2 mV to ± 700 mV Width: 0.1 ms to 2.0 ms Ascending time: 10 μ s to 100 μ s		
Pulse Rejection	Pulse is marked if the requirements of IEC 60601-2-27: 2011, Sect. 201.12.1.101.12 are met: Amplitude: ± 2 mV to ± 700 mV Width: 0.1 ms to 2.0 ms Ascending time: 10 μ s to 100 μ s	± 2 mV to ± 700 mV and widths from 0.1 ms to 2.0 ms	
Maximum start-up alarm time for Tachycardia			
Ventricular Tachycardia 1 mV 206bpm	Gain 1.0: 10 s	Gain 1.0 Range 6.1 to 6.9 seconds, Average 6.5 seconds	Different
Ventricular Rhythm Ventricular Bradycardia	Gain 0.5: 10 s	Gain 0.5, Range 6.5 to 8.4 seconds, Average 7.2 seconds	
	Gain 2.0: 10 s	Gain 2.0, Range 5.9 to 6.7 seconds, Average 6.3 seconds	
Ventricular Tachycardia 2 mV 195bpm	Gain 1.0: 10 s	Gain 1.0, Range 5.7 to 6.5 seconds, Average 6.1 seconds	
	Gain 0.5: 10 s	Gain 0.5, Range 5.4 to 6.2 seconds, Average 5.8 seconds	
	Gain 2.0: 10 s	Gain 2.0, Range 5.3 to 6.1 seconds, Average 5.7 seconds	
Tall T-wave Rejection	Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.17 minimum recommended 1.2 mV T-Wave amplitude	Exceeds ANSI/AAMI EC 13 Sect. 3.1.2.1(c) minimum recommended 1.2 mV T-Wave amplitude.	
Heart Rate Averaging Method	Method1. Heart rate is computed by excluding the minimum and maximum values from the 12 most recent RR	Three different methods are used: Normally, heart	Different

	<p>intervals and averaging the residual 10 RR intervals.</p> <p>Method 2.If each of three consecutive RR intervals is greater than 1200ms, then the four most recent RR intervals are averaged to compute the HR.</p>	<p>rate is computed by averaging the 12 most Recent RR intervals.</p> <p>For runs of PVCs, up to 8 RR intervals are averaged to compute the HR. If each of 3 consecutive RR intervals is greater than 1200 ms (that is, rate less than 50 bpm), then the 4 most recent RR intervals are averaged to compute the HR.</p>	
Accuracy of Heart Rate Meter and Response to Irregular Rhythm	<p>Complied with IEC 60601-2-27: 2011, Sect. 201.7.9.2.9.101 b) 4), the HR value after 20 seconds of stabilization is displayed as follows:</p> <p>Ventricular bigeminy: 80 bpm±1 bpm</p> <p>Slow alternating ventricular bigeminy: 60 bpm±1 bpm</p> <p>Rapid alternating ventricular bigeminy: 120 bpm±1 bpm</p> <p>Bidirectional systoles: 91 bpm±1 bpm</p>	<p>Ventricular bigeminy: 80 bpm</p> <p>Slow alternating ventricular bigeminy: 60 bpm</p> <p>Rapid alternating ventricular bigeminy: 120 bpm</p> <p>Bidirectional systoles: 90 bpm</p>	Different
Response time of Heart Rate Meter to Change in HR	<p>HR range: 80 bpm to 120 bpm</p> <p>Range : Within 11 s</p> <p>HR range: 80 bpm to 40 bpm</p> <p>Range : Within 11 s</p>	<p>HR change from 80 to 120 bpm:</p> <p>Range: [6.4 to 7.2 seconds] Average: 6.8 seconds</p> <p>HR change from 80 to 40 bpm:</p> <p>Range: [5.6 to 6.4 sec] Average: 6.0 seconds</p>	Different
RESP Function			
Respiration excitation waveform	Sinusoid, 62.8 kHz ($\pm 10\%$), <500 μ A	Sinusoidal signal, 260 μ A, 39 kHz	Different
RR	Adult: 0 rpm to 120rpm	Adult/pedi: 0 to	Different

Measuring Range	Pediatric/neonate: 0 rpm to 150rpm		120 rpm Neo: 0 to 170 rpm		
Accuracy	Adult: 6 to 120 rpm: ± 2 rpm, 0 to 5 rpm: not specified Neo/Ped: 6 to 150 rpm: ± 2 rpm 0 to 5 rpm: not specified		at 0 to 120 rpm ± 1 rpm at 120 to 170 rpm ± 2 rpm	Different	
Resolution	1 rpm		1 rpm	Same	
Waveform bandwidth	0.2Hz to 2.5Hz (-3dB)		0.3 to 2.5 Hz (-6 dB)	Different	
Apnea Alarm Time Setup	10s, 15s, 20s, 25s, 30s, 35s, 40s;		10 to 40 seconds 5 second steps	Different	
NIBP Function					
Principle of Operation	oscillation(EDAN, SunTech NIBP)		oscillation	Same	
Measurement Range	Adult			Different	
	Systolic	EDAN NIBP	40 mmHg ~ 270 mmHg		30 to 270 mmHg
		SunTech NIBP	60 mmHg ~ 250 mmHg		
	Diastolic	EDAN NIBP	10 mmHg ~ 215 mmHg		10 to 245 mmHg
		SunTech NIBP	30 mmHg ~ 190 mmHg		
	Mean	EDAN NIBP	20 mmHg ~ 235 mmHg		20 to 255 mmHg
		SunTech NIBP	40 mmHg ~ 210 mmHg		
	Pediatric				
	Systolic	EDAN NIBP	40 mmHg ~ 230 mmHg		30 to 180 mmHg (4 to 24 kPa)
		SunTech NIBP	40 mmHg ~ 230 mmHg		
	Diastolic	EDAN NIBP	10 mmHg ~ 180 mmHg		10 to 150 mmHg
		SunTech NIBP	20 mmHg ~ 160 mmHg		
	Mean	EDAN NIBP	20 mmHg ~ 195 mmHg		20 to 160 mmHg
		SunTech NIBP	30 mmHg ~ 175 mmHg		
Neonate					
Systolic	EDAN NIBP	40 mmHg ~ 135 mmHg	30 to 130 mmHg (4 to 17 kPa)		

		SunTec h NIBP	40 mmHg ~130 mmHg		
	Diastolic	EDAN NIBP	10 mmHg ~ 100 mmHg	10 to 100 mmHg	
		SunTec h NIBP	20 mmHg ~ 90 mmHg		
	Mean	EDAN NIBP	20 mmHg ~ 110 mmHg	20 to 120 mmHg	
		SunTec h NIBP	30 mmHg ~ 100 mmHg		
Accuracy	Max standard deviation: 8 mmHg(EDAN, SunTech); Max mean error: ± 5 mmHg			Max. Std. Deviation: 8 mmHg (1.1 kPa) Max. Mean Error: ± 5 mmHg (± 0.7 kPa)	Same
Pressure Resolution	1mmHg(EDAN, SunTech);			1mmHg	Same
Maximum measuring period	Adult/Pediatric 120s Neonate 90s			Maximum time: 180 seconds (adult/pediatric) 90 seconds (neonates)	Different
Overpressure protection	Adult	297 \pm 3mmHg(EDAN) <300mmHg(SunTech)		>300 mmHg (40 kPa) >2 sec	Different
	Pediatric	240 \pm 3mmHg(EDAN) <300mmHg(SunTech)		>300 mmHg (40 kPa) >2 sec	
	Neonate	147 \pm 3mmHg(EDAN) <150mmHg(SunTech)		>150 mmHg (20 kPa) >2 sec	
Measuring interval in AUTO Mode	1/2/3/4/5/10/15/30/60/90/120/240/480 min(EDAN) 1/2/3/4/5/10/15/30/60/90/120/240/480 min(SunTech)			1, 2, 2.5, 3, 5, 10, 15, 20, 30, 45, 60 or 120 minutes	Different
Continuous	5min, interval is 5s			5 minutes	Same
SpO2 Function (EDAN)					
Measuremen t Range	0-100%			0 to 100 %	Same
Accuracy	Adult /Pediatric ± 2 % (70% to 100% SpO ₂), Undefined (0 to 69% SpO ₂) Neonate ± 3 % (70% to 100% SpO ₂), Undefined (0 to 69% SpO ₂)			Philips Reusable Sensors: M1191A, M1191AL, M1191ANL, M1191B, M1191BL,	Different

		M1192A, M1192AN = 2 % (70 % to 100 %) M1193A, M1193AN, M1194A, M1194AN, M1195A, M1195AN, M1196A = 3 % (70 % to 100 %) M1191T, M1192T, M1193T (Adult), M1196T = 3% (70% to 100%) M1193T (Neonate) = 4 % (70 % to 100 %)	
Resolution	1 %	1 %	Same
Pulse Rate			
Measuring Range	25 bpm to 300 bpm	30 to 300 bpm	Different
Accuracy	±2bpm	±2 % or 1 bpm, whichever is greater	Different
Resolution	1 bpm	1 bpm	Same
SpO2 Function (Nellcor)			
Measurement Range	1% to 100%	1% to 100%	Same
Accuracy	DS-100A, OXI-A/N(Adult): ± 3% (70% to 100% SpO ₂) OXI-A/N(Neonate): ± 4% (70% to 100% SpO ₂)	Philips Reusable Sensors: M1193A, M1193AN, M1194A, M1194AN, M1195A, M1195AN, M1196A = 3 % (70 % to 100 %) M1191T, M1192T, M1193T (Adult), M1196T = 3% (70% to 100%) M1193T (Neonate)	Same

		= 4 % (70 % to 100 %)	
Resolution	1 %	1 %	Same
Pulse Rate			
Measuring Range	20bpm to 300bpm	30 to 300 bpm	Different
Accuracy	± 3bpm (20bpm to 250bpm)	±2 % or 1 bpm, whichever one is greater	Different
Resolution	1 bpm	1 bpm	Same
Temperature Function			
Measurement Range	0 to 50°C	-1 to +49°C (30 to 113°F)	Different
Accuracy (not including sensor)	±0.1 °C	±0.1°C (±0.2°F)	Same
Resolution	0.1°C	0.1°C (±0.1°F)	Same
Average Time Constant	≤30 s	Less than 10 seconds	Different
IBP Function			
Measurement Range	-50 to +300 mmHg	-40 to 360 mmHg	Different
Accuracy (not including sensor)	± 2 % or ±1 mmHg, whichever is greater	4 % of reading or ±4 mmHg (±0.5 kPa), whichever is greater	Different
Resolution	1 mmHg	1 mmHg	Same
Transducer	5 (µV/V/mmHg)300 to 3000 Ω	Load Impedance:200 to 2000 Ω (resistive) Output Impedance:"3000 Ω (resistive)	Different
Zero	Range: ±200 mmHg	±200 mmHg (±26 kPa)	Same
Electronic Safety			
Anti-electroshock type	Class II	Class II	Same
Anti-electroshock degree	ECG (RESP), TEMP, IBP CF SpO ₂ ,NIBP,CO ₂ BF	CF	Different

Working system	Continuous operation equipment	Continuous operation equipment	Same
Environmental Specifications			
Temperature Range			
Operating	0°C to +40°C	0 to 40°C (32 to 104°F)	Same
Storage including transportation	-30°C to +70°C	-20 to 60°C (-4 to 140°F)	Different
Humidity Range			
Operating	15% to 95% (non-condensing)	15 % to 95 % Relative Humidity (RH)	Same
Storage including transportation	15% to 95% (non-condensing)	5 % to 95 % Relative Humidity (RH)	Different
Altitude Range			
Operating	615hPa to 1060hPa (DC-DC power supply)(-400 m to 4000 m) 680hPa to 1060hPa (AC to DC power supply)(-400m to 3000m)	-500 m to 3000 m (10000 ft)	Different
Storage including transportation	615hPa to 1060hPa (-400 m to 4000 m)	-500 m to 4600 m (15000 ft)	
Physical Characteristics			
Weight	iM20 : <1.5kg EFM : <0.58 kg	1.25 kg	Different
Dimensions	iM20: 185 mm (L) × 85.3 mm (W) × 116 mm (H) EFM: 207 mm (L) × 93.4 mm (W) × 116 mm (H)	(W x H x D) 188 x 99 x 86 mm	
Display Specification			
Description	5 inches LCD	72 x 54 mm (2.8 x 2.1 in)	Different
Resolution	800x480	320 x 240	
Power Supply			
Power consumption	<25w(Max)	<12 W average <30 W while battery is loading	Different
Power input	11.1V to 19.8VDC	36 to 60 V DC floating	
Current	1.27~2.3A	0.7 to 0.4 A	

AC-DC Power supply			
Line Voltage	100~240Vac	100 to 240 V ~	Same
Output Voltage	15V±5%dc, 24VA	36 to 60 V DC floating	Different
Frequency	50/60 Hz ~	50/60 Hz ~	Same
DC-DC Power supply			
Line Voltage	10~16Vdc	N/A	Different
Output Voltage	15V±5%dc	N/A	
Standard Compliance			
General requirement	IEC 60601-1:2005	IEC 60601-1:1988 + A1:1991 + A2:1995	Different
Special requirement	IEC 60601-2-25: 2011	IEC 60601-2-25:1993 + A1:1999	
	IEC 60601-2-27: 2011	IEC 60601-2-27:2005	
	IEC 60601-2-51: 2003	IEC 60601-2-51:2003	
	AAMI EC11	AAMI EC11	
	EC13:1991/2002.	EC13:1991/2002	
	IEC 80601-2-30: 2009	IEC 60601-2-30:1999	
	IEC 60601-2-34: 2011	IEC 60601-2-34:2000	
	ISO 80601-2-61: 2011	ISO 9919:2005	
	EN 12470-4: 2000+ A1: 2009	EN 12470-4:2000	
	ISO 80601-2-55: 2011	EN ISO 21647:2004 +Cor.1:2005	
	ISO 80601-2-56: 2009	EN 12470-4:2000	
	ISO 81060-2: 2009	--	
	IEC 60601-2-49: 2011	IEC 60601-2-49:2001).	
EMC	IEC 60601-1-2:2007	IEC 60601-1-2:2001 + A1:2004.	
Alarm	IEC 60601-1-8:2006	IEC60601-1-8:2003	
Biocompatibility	Compliance with ISO10993-1 ISO 10993-5,ISO 10993-5-10	Compliance with ISO10993-1 ISO 10993-5,ISO	

		10993-5-10	
Out-Of-Hospital Transport - Standards Compliance			
Out-Of-Hospital Transport - Standards Compliance			
Shock Tests	According to IEC TR 60721-4-7, Class 7M3. Test procedure according to IEC/EN60068-2-27 (peak acceleration up to 100g).	According to IEC TR 60721-4-7, Class 7M3. Test procedure according to IEC/EN 60068-2-27 (peak acceleration up to 100g).	Same
Random Vibration	According to IEC TR 60721-4-7, Class 7M3. Test procedure according to IEC/EN 60068-2-64 (RMS acceleration 5g).	According to IEC TR 60721-4-7, Class 7M3. Test procedure according to IEC/EN 60068-2-64 (RMS acceleration 5g).	Same
Sinusoidal Vibration	According to EN1789:2007+A: 2010, 6.4.1 vibration test, Test procedure according to IEC/EN 60068-2-6 (acceleration up to amplitude 2g).	According to IEC TR 60721-4-7, Class 7M3. Test procedure according to IEC/EN 60068-2-6 (acceleration up to amplitude 2g).	Different
Bump	According to EN1789:2007+A: 2010, 6.4.1 Bump test, Test procedure according to IEC/EN 60068-2-6 (acceleration up to amplitude 15g).	--	Different
Drop Test	according to EN1789:2007+A:2010, Test Procedure according to EN 60068-2-32 (height 1.2 m).	According to EN1789 (covers also IEC TR 60721-4-7 and Class 7M3). Test procedure according to EN 60068-2-32 (height 0.75 m).	Different
Degrees of Protection	provided by enclosures according to IEC/EN 60529: IP44	provided by enclosures according to	Different

		IEC/EN 60529: IP32	
Medical Vehicles and Equipments	EN1789:2007+A: 2010 Medical vehicles and their equipment - Road ambulances (chapter 6 – Medical Devices).	EN 1789 +A1:2003 Medical vehicles and their equipment - Road ambulances (chapter 6 – Medical Devices).	Same
Radiated Susceptibility	20 V/m according to EN ISO 9919 (SpO2) and EN ISO 21647 (CO2).	20 V/m according to EN ISO 9919 (SpO2) and EN ISO 21647 (CO2).	Same
Alarm System			
Alarm Categories	Physiological alarms Technical alarms Prompt information	Physiological alarms Technical alarms Prompt information	Same
Alarm Levels	High level alarms Medium level alarms Low level alarms	High level alarms Medium level alarms Low level alarms	Same
Alarm Modes	Visual alarms Audible alarms Alarm messages Parameter flashes Reminder Tones	Visual alarms Audible alarms Alarm messages Parameter flashes Reminder Tones	Same

Comparison to Reference Device iM70

Item	Proposed device, iM20	Predicate device, iM70	Comparison Result
K#	Current Submission	K131971	
PR from NIBP			
Measurement range	40 to 240 bpm(EDAN)	40 to 240 bpm	Same
	30 bpm ~220bpm(SunTech)		Different
Accuracy	±3bpm or 3.5%, whichever is greater(EDAN);	±3bpm or 3.5%, whichever is greater	Same
	±3bpm or ±2%, whichever is greater(SunTech);	±3bpm or 3.5%, whichever is greater	Different
CO2 Function			
Measuring Range			

EtCO ₂	0 mmHg ~ 150 mmHg	0 to 150 mmHg (0 to 20.0 kPa)	Same
FiCO ₂	3 mmHg ~50 mmHg	3 mmHg to 50 mmHg	Same
AwRR	2 rpm ~ 150 rpm (Sidestream)	2 to 150 rpm	Same
Resolution			
EtCO ₂	1mmHg	1.0 mmHg (0.1 kPa)	Same
FiCO ₂	1mmHg	1mmHg	Same
AwRR	1 rpm	±1 rpm	Same
EtCO₂ Accuracy			
0 to 40 mmHg	± 2 mmHg	±2.0 mmHg (±0.29 kPa)	Same
41 to 70 mmHg	± 5 %	±5 % of reading	Same
71 to 100 mmHg	± 8 %	±8 % of reading	Same
101 to 150 mmHg	± 10 %	±10 % of reading	Same
RESP measurement value exceeds 80rpm (sidestream)	± 12 %	±12 % of actual	Same
AwRR Accuracy	± 1 rpm	± 1 rpm	Same
Sample Gas Flow rate (sidestream)	50 ±10 ml/min	50±10ml/min	Same
O₂ Compensation			
Range	0 ~ 100%	0 ~ 100%	Same
Resolution	1%	1%	Same
Default	16%	16%	Same
Barometric pressure compensation	User setup	User setup	Same
Anesthetic Gas Compensation			
Range	0 ~ 20%	0 ~ 20%	Same
Resolution	0.1%	0.1%	Same
Default	0.0%	0.0%	Same
Balance Gas Compensation	Room air, N ₂ O, helium	Room air, N ₂ O, helium	Same
Stability			
Short Term	Drift over 4 hours < 0.8 mmHg	Drift over 4 hours	Same

Drift		< 0.8 mmHg	
Long Term Drift	120 hours	120 hours	Same
Total System Response Time	4.7 s	4.7 s	Same
Alarm Type	EtCO ₂ , FiCO ₂ , AwRR	EtCO ₂ , FiCO ₂ , AwRR	Same
Apnea Alarm Delay	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
Data Sample Rate	100 Hz	100 Hz	Same
Sensor Response Time (sidestream)	< 3 seconds, including transport time and rise time	< 3 seconds, including transport time and rise time	Same
Interfering Gas and Vapor Effects on EtCO₂ Measurement Values			
Nitrous oxide 60%	Dry and Saturated Gas 0 – 40 mmHg: ± 1 mmHg additional error	Dry and Saturated Gas 0 – 40 mmHg: ± 1 mmHg additional error	Same
Halothane 4%	41 – 70 mmHg: ± 2.5% additional error	41 – 70 mmHg: ± 2.5% additional error	
Desflurane 5%	71 – 100 mmHg: ± 4% additional error 101 – 150 mmHg: ± 5% additional error	71 – 100 mmHg: ± 4% additional error 101 – 150 mmHg: ± 5% additional error	
Enflurane 5%	*Additional worst case error when compensation for P _B , O ₂ , N ₂ O, anesthetic agents, or helium is correctly selected for the actual fractional gas constituents present.	*Additional worst case error when compensation for P _B , O ₂ , N ₂ O, anesthetic agents, or helium is correctly selected for the actual fractional gas constituents present.	
Isoflurane 5%			
Sevoflurane 80%	Desflurane: The presence of desflurane in the exhaled breath at concentrations greater than 5% will positively bias Carbon Dioxide values by up to an additional 3 mmHg at 38mmHg.	Desflurane: The presence of desflurane in the exhaled breath at concentrations greater than 5% will positively bias Carbon Dioxide values by up to an additional 3 mmHg at 38mmHg.	
Xenon 50%	Xenon: The presence of Xenon in the exhaled breath will negatively bias Carbon Dioxide values by up to an additional 5 mmHg at 38mmHg.	Xenon: The presence of Xenon in the exhaled breath will negatively bias Carbon Dioxide values by up to an additional 5 mmHg at 38mmHg.	
Helium 15%			

		<p>Desflurane: The presence of desflurane in the exhaled breath at concentrations greater than 5% will positively bias Carbon Dioxide values by up to an additional 3 mmHg at 38mmHg.</p> <p>Xenon: The presence of Xenon in the exhaled breath will negatively bias Carbon Dioxide values by up to an additional 5 mmHg at 38mmHg.</p>	
Barometric Pressure on EtCO₂ Measurement Values			
0 – 40 mmHg	± 1 mmHg additional error	± 1 mmHg additional error	Same
41 – 70 mmHg	± 2.5% additional error	± 2.5% additional error	Same
71 – 100 mmHg	± 4% additional error	± 4% additional error	Same
101 – 150 mmHg	± 5% additional error	± 5% additional error	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)	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	Same

dBm)		802.11b CCK 15 dBm for 802.11g/n OFDM	
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As seen in the comparison tables, the subject and predicate devices have similar design features and performance specifications. The main technological differences between the subject and predicate devices are minor differences, and do not raise different questions of safety or effectiveness. As demonstrated in the non-clinical and clinical testing, the different technological characteristics do not affect the safety and effectiveness of the Edan iM20 system.

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 iM20 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 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 iM20 Patient Monitor device, consisting of all the modules and accessories in the system. The system complies with the IEC 60601-1:2005/A1: 2012 for safety and the IEC 60601-1-2:2007 standard for EMC.

Bench Testing

Bench testing was conducted on the iM20 Patient Monitor device, consisting of all the modules and accessories in the system. The system complies with the IEC 60601-1-8: 2006, IEC 60601-2-25: 2011, IEC 60601-2-27: 2011, 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 and ISO 80601-2-61: 2011 standards for performance effectiveness.

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:

Clinical testing required by FDA specific guidance on Non-Invasive Blood Pressure (NIBP) Monitor is conducted per ISO 81060-2: 2013 Non-Invasive Sphygmomanometers - Part 2: Clinical Validation of Automated Measurement Type.

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 iM20 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 iM20 Patient Monitor devices are substantially equivalent to the predicate devices.