August 10, 2022

CAF Medical Solutions Inc.
% Juan Tezak
Consultant
Compliance 4 Device
118 W Prive Cr.
Delray Beach, Florida 33445

Re: K221879
Trade/Device Name: Patient Monitor, models LM-8, LM-10, LM-12 and LM-15
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, DST, MLD, DRT, DXN, DSK, FLL, DQA, CCK, CBQ, NHO, NHQ, NHP, CBS, CBR, CCL, DSB, BZK, BZQ, DPS, DRG
Dated: June 28, 2022
Received: June 28, 2022

Dear Juan Tezak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer Shih
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221879

Device Name
Patient Monitor, models LM8, LM10, LM12 and LM15

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 and pediatrics. The monitors are intended for use by trained healthcare professionals in hospital environments.

The LM-8 monitor monitors parameters such as ECG (3-lead, 5-lead, 12-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (dual-IBP, NIBP), Temperature (dual-TEMP), Expired CO2 and Quick Temperature (Quick TEMP).

The LM-10 monitor monitors parameters such as ECG (3-lead, 5-lead, 12-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (2/4 channels IBP, NIBP), Cardiac Output (C.O.), Temperature (dual-TEMP) and Expired CO2.

The LM-12 monitor monitors parameters such as ECG (3-lead, 5-lead, 12-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (2/4 channels IBP, NIBP), Cardiac Output (C.O.), Temperature (dual-TEMP), Expired CO2 and Anesthetic gas (AG).

The LM-15 monitor monitors parameters such as ECG (3-lead, 5-lead, 12-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (2/4 channels IBP, NIBP), Cardiac Output (C.O.), Temperature (dual-TEMP), Expired CO2 and Anesthetic gas (AG).

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

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.

510(k) Summary

Patient Monitor, models LM-8, LM-10, LM-12 and LM-15
June, 2022

ADMINISTRATIVE INFORMATION

Applicant	CAF Medical Solutions Inc. 17539 Roberts Road, Hockley TX 77477 USA E-mail: c.ortiz@cafmedical.com
Establishment Registration Number	
Official Contact	Oscar Arriaga Yamin Legal Representative 17539 Roberts Road, Hockley TX 77477 USA Phone: +1 713 614 7049 E-mail: c.ortiz@cafmedical.com
Representative/Consultant	Juan Tezak Carlos Marín Compliance4Devices 118 W Prive Cr. Delray Beach Fl, 33445 Phone: +1 561-789-2411 E-mail: compliance4devices@gmail.com

DEVICE AND CLASSIFICATION NAME

Device Trade Name:	Patient Monitor, models LM-8, LM-10, LM-12 and LM-15
Regulatory Class:	Class II
Prior Submission:	No prior submission
Device name, classification and product code:	· 870.1025 monitor, physiological, patient (with arrhythmia detection or alarms)/ MHX · 870.1025 Detector and Alarm, Arrhythmia/ DST · 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

Predicate Device Information

Predicate Devices:

- K113623. Patient Monitor Models iM50 and iM80. Edan Instruments, Inc.
- K131971. Patient Monitor Models iM60 and iM70. Edan Instruments, Inc.

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 and pediatrics. The monitors are intended for use by trained healthcare professionals in hospital environments.

The LM-8 monitor monitors parameters such as ECG (3-lead, 5-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (dual-IBP, NIBP), Temperature (dual-TEMP), Expired CO2 and Quick Temperature (Quick TEMP).

The LM-10 monitor monitors parameters such as ECG (3-lead, 5-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (2/4 channels IBP, NIBP), Cardiac Output (C.O.), Temperature (dual-TEMP) and Expired CO2.

The LM-12 monitor monitors parameters such as ECG (3-lead, 5-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (2/4 channels IBP, NIBP), Cardiac Output (C.O.), Temperature (dual-TEMP), Expired CO2 and Anesthetic gas (AG).

The LM-15 monitor monitors parameters such as ECG (3-lead, 5-lead, 12-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (2/4 channels IBP, NIBP), Cardiac Output (C.O.), Temperature (dual-TEMP), Expired CO2 and Anesthetic gas (AG).

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

The monitors are not intended for MRI environments.

Device Description

LM-8, LM-10, LM-12 and LM-15, patient monitor integrates parameter measuring modules, display and recorder in one device, featuring in compactness, lightweight and portability. Replaceable built-in battery facilitates patient transport. Large high-resolution display provides clear view of 10 waveforms and full monitoring parameters. Patient Monitor can monitor vital signal such as ECG, respiration (RESP), non-invasive blood pressure (NIBP), oxygen saturation of the blood (SpO2), temperature (TEMP), invasive blood pressure (IBP), cardiac output (C.O.), CO2 and anesthetic gas (AG). Those signals are digitized, processed and examined for alarm conditions, after that presents all those information on the color TFT display. The monitor also provides advantageous operating control for the user.

LM-8, LM-10, LM-12 and LM-15, patient monitor have the same intended use. The differences are as follows:

Patient Monitor	Difference LCD	Difference Parameter
LM-8	8.4 inch	ECG RESP TEMP QuickTEMP SpO2 NIBP IBP CO2 3/5-lead ECG
LM-10	10.4 inch	ECG RESP TEMP SpO2 NIBP IBP CO2 C.O. 3/5-lead ECG
LM-12	12.1 inch	ECG RESP TEMP SpO2 NIBP IBP CO2 C.O. AG 3/5-lead ECG
LM-15	15 inch	ECG RESP TEMP SpO2 NIBP IBP CO2 C.O. AG 3/5/12-lead ECG

Contraindications:

There are no known contraindications for use.

Equivalence to Marketed Device

Patient Monitor, models LM-8, LM-10, LM-12 and LM-15 is substantially equivalent to the predicated. In further support of a substantial equivalence determination, here-under is a comparison chart with the submitted device and predicate device.

Table 1. Comparison with predicate device for Summary

ITEM	PROPOSED DEVICE	K113623 PREDICATE DEVICE	K131971 PREDICATE DEVICE	COMPARISON RESULT
		General Features		
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 and pediatrics. The monitors are intended for use by trained healthcare professionals in hospital environments. The LM-8 monitor monitors parameters such as ECG (3-lead, 5-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (dual-IBP, NIBP), Temperature (dual-TEMP), Expired CO2 and Quick Temperature (Quick TEMP). The LM-10 monitor monitors parameters such as ECG (3-lead, 5-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (2/4 channels IBP, NIBP), Cardiac Output (C.O.), Temperature (dual-TEMP) and Expired CO2. The LM-12 monitor monitors parameters such as ECG (3-lead, 5-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (2/4 channels IBP, NIBP), Cardiac Output (C.O.), Temperature (dual-TEMP), Expired CO2 and Anesthetic gas (AG). The LM-15 monitor monitors parameters such as ECG (3-lead, 5-lead, 12-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (2/4 channels IBP, NIBP), Cardiac Output (C.O.), Temperature (dual-TEMP), Expired CO2 and Anesthetic gas (AG). The arrhythmia detection and ST Segment analysis are intended for adult and pediatric patients. The monitors are not intended for MRI environments.	iM80: The monitor monitors parameters such as ECG (3-lead, 5-lead, 12-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (2/4 channels IBP NIBP), Cardiac Output (CO), Temperature (dual-TEMP), Expired CO2 and Anesthetic gas (AG). 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. iM50: The monitor monitors parameters such as ECG (3-lead, 5-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (dual-IBP, NIBP), Temperature (dual-TEMP), Expired CO2 and Quick Temperature (Quick TEMP). The monitor is equipped with alarms that indicate system faults (such as loose	iM60: The iM60 monitor monitors parameters such as ECG (3-lead, 5-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (2/4 channels IBP NIBP), Cardiac Output (CO), Temperature (dual-TEMP) and Expired CO2. 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. iM70: The iM70 monitor monitors parameters such as ECG (3-lead, 5-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (2/4 channels IBP NIBP), Cardiac Output (CO), Temperature (dual-TEMP), Expired CO2 and Anesthetic gas (AG). The monitor is equipped with alarms that indicate system faults (such	Similar

ITEM	PROPOSED DEVICE	K113623 PREDICATE DEVICE	K131971 PREDICATE DEVICE	COMPARISON RESULT
		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.	as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both.	
Contraindications	It is not intended for use in patient's home or residence, or when it has not been ordered by a physician.	It is not intended for use in patient's home or residence, or when it has not been ordered by a physician.	It is not intended for use in patient's home or residence, or when it has not been ordered by a physician.	Same
Test Summary	Software testing Hardware testing Safety testing Environment test Risk analysis Final validation	Software testing Hardware testing Safety testing Environment test Risk analysis Final validation	Software testing Hardware testing Safety testing Environment test Risk analysis Final validation	Same

Features by Model

Feature	Proposed Models				Predicate Models				Same
	LM-8	LM-10	LM-12	LM-15	iM50	iM80	iM60	iM70	
Monitors SpO2 parameters	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Same
Monitor NIBP parameters	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Same
Monitors ECG parameters	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Same
Monitor RESP parameters	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Same
Monitors TEMP parameters	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Same
Monitors CO2 parameters	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Same
Monitor IBP parameters	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Same
Monitor C.O. parameters	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Same
Monitors AG parameters	No	No	Yes	Yes	No	Yes	No	Yes	Same

ITEM	PROPOSED DEVICE				K113623 PREDICATE DEVICE		K131971 PREDICATE DEVICE		COMPARISON RESULT
User may select different monitoring parameters in according with the requirement	Yes	No	No	Yes	Yes	Yes	No	No	Same
Screen size	8.4 inches	10.4 inches	12.1 inches	15 inches	8.4 inches	15 inches	10.4 inches	12.1 inches	Same
Touch screen	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Same
Supports online software update and networking	No	No	No	Yes	No	Yes	No	No	Same
Alarms to indicate system failures and/or out-of-range parameters.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Same
EDAN SP02 module available for this model	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Same
Nellcor SP02 module available for this model	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Same
EDAN NIBP module available for this model	No	No	Yes	Yes	No	Yes	No	Yes	Same
OMROM M3600 module for NIBP available for this model	No	No	Yes	Yes	No	Yes	No	Yes	Same
Suntech NIBP module available for this model	No	No	No	Yes	No	Yes	No	No	Same
Parameters by Module									
ECG module									
Lead Mode	***3 Electrodes; 5 Electrodes and 12 Electrodes.***				***3 Electrodes; 5 Electrodes and 12 Electrodes.***				***Same***
Arrhythmia analyses	***ASYSTOLE, VFIB/VTAC, COUPLET, VT> 2, BIGEMINY, TRIGEMINY, VENT, R on T, PVC, TACHY, BRADY, MISSED BEATS, IRR, VBRADY, PNC, PNP***				***ASYSTOLE, VFIB/VTAC, COUPLET, VT> 2, BIGEMINY, TRIGEMINY, VENT, R on T, PVC, TACHY, BRADY, MISSED BEATS, IRR, VBRADY, PNC, PNP***				***Same***
ST value									
Measurement Range	***-2.0 mV to +2.0 mV***				***-2.0 mV to +2.0 mV***				***Same***
Pace									
Pulse Indicator	***Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to 2.0 ms Ascending time: 10 µs to 100 µs***				***Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to 2.0 ms Ascending time: 10 µs to 100 µs***				***Same***
PVC									
Range	***ADU: (0 to 300) PVCs/ min PED/NEO: (0 to 350) PVCs/ min***				***ADU: (0 to 300) PVCs/ min PED/NEO: (0 to 350) PVCs/ min***				***Same***

<table>
<tr><th>ITEM</th><th>PROPOSED DEVICE</th><th>K113623
PREDICATE DEVICE</th><th>K131971
PREDICATE DEVICE</th><th>COMPARISON RESULT</th></tr>
<tr><td colspan="5">HR</td></tr>
<tr><td>Measurement range</td><td colspan="2">ADU: 15 bpm to 300 bpm
PED/NEO: 15 bpm to 350 bpm</td><td>ADU: 15 bpm to 300 bpm
PED/NEO: 15 bpm to 350 bpm</td><td>Same</td></tr>
<tr><td colspan="5">RESP module</td></tr>
<tr><td>Principle of Operation</td><td colspan="2">Impedance between RA-LL, RA-LA</td><td>Impedance between RA-LL, RA-LA</td><td>Same</td></tr>
<tr><td>Measurement Range</td><td colspan="2">Adult: 0 to 120 rpm
Pediatric/neonate: 0 to 150 rpm</td><td>Adult: 0 to 120 rpm
Pediatric/neonate: 0 to 150 rpm</td><td>Same</td></tr>
<tr><td colspan="5">NIBP module (EDAN)</td></tr>
<tr><td>Technique</td><td colspan="2">Oscillometry</td><td>Oscillometry</td><td>Same</td></tr>
<tr><td>Measurement Range</td><td colspan="2">Measurement range:
<table><tr><th></th><th>Adult</th><th>Pediatric</th><th>Neonate</th></tr><tr><td>Systolic</td><td>40-270</td><td>40-250</td><td>40-135</td></tr><tr><td>Diastolic</td><td>10-215</td><td>10-200</td><td>10-100</td></tr><tr><td>Mean</td><td>20-235</td><td>20-235</td><td>20-110</td></tr></table></td><td>Measurement range:
<table><tr><th></th><th>Adult</th><th>Pediatric</th><th>Neonat</th></tr><tr><td>Systolic</td><td>40-270</td><td>40-250</td><td>40-135</td></tr><tr><td>Diastolic</td><td>10-215</td><td>10-200</td><td>10-100</td></tr><tr><td>Mean</td><td>20-235</td><td>20-235</td><td>20-110</td></tr></table></td><td>Same</td></tr>
<tr><td colspan="5">PR from NIBP</td></tr>
<tr><td>Measurement range</td><td colspan="2">40 bpm to 240 bpm</td><td>40 bpm to 240 bpm</td><td>Same</td></tr>
<tr><td colspan="5">SpO2 module (EDAN)</td></tr>
<tr><td>Measurement Range</td><td colspan="2">SpO2: 0% to 100%
Pulse Rate: 25 to 300 bpm</td><td>SpO2: 0% to 100%
Pulse Rate: 25 to 300 bpm</td><td>Same</td></tr>
<tr><td colspan="5">Temperature module</td></tr>
<tr><td>Number of channels</td><td colspan="2">2</td><td>2</td><td>Same</td></tr>
<tr><td>Measurement Range</td><td colspan="2">0°C to 50°C (32°F to 122°F)</td><td>0°C to 50°C (32°F to 122°F)</td><td>Same</td></tr>
<tr><td colspan="5">IBP module</td></tr>
<tr><td>Measurement Range</td><td colspan="2">PA/PAWP: (-6 to +120) mmHg
CVP/RAP/LAP/ICP: (-10 to +40) mmHg
P1/P2: (-50 to +300) mmHg</td><td>PA/PAWP: (-6 to +120) mmHg
CVP/RAP/LAP/ICP: (-10 to +40) mmHg
P1/P2: (-50 to +300) mmHg</td><td>Same</td></tr>
<tr><td colspan="5">C.O. Module</td></tr>
<tr><td>Technique</td><td colspan="2">Thermodilution Technique</td><td>Thermodilution Technique</td><td>Same</td></tr>
<tr><td>Measurement range</td><td colspan="2">C.O.: 0.1 to 20L/min
TB: 23°C to 43°C (73.4°F to 109.4°F)
TI: -1°C to 27°C (30.2°F to 80.6°F)</td><td>C.O.: 0.1 to 20L/min
TB: 23°C to 43°C (73.4°F to 109.4°F)
TI: -1°C to 27°C (30.2°F to 80.6°F)</td><td>Same</td></tr>
<tr><td colspan="5">CO2 Module</td></tr>
</table>

ITEM	PROPOSED DEVICE	K113623 PREDICATE DEVICE / K131971 PREDICATE DEVICE	COMPARISON RESULT
Intended Patient	*Adult, pediatric, neonatal*	*Adult, pediatric, neonatal*	*Same*
Measure Parameters	*$EtCO_2$, $FiCO_2$, AwRR*	*$EtCO_2$, $FiCO_2$, AwRR*	*Same*
Measuring Range	*CO2: 0mmHg to 150mmHg (0 % to 20%)* *AwRR: 2rpm to 150rpm*	*CO2: 0mmHg to 150mmHg (0 % to 20%)* *AwRR: 2rpm to 150rpm*	*Same*
AG module (EDAN G7 module)			
Measure Parameters	*CO_2, N_2O, O_2, HAL, ISO, ENF, SEV, DES, awRR, MAC.*	*CO_2, N_2O, O_2, HAL, ISO, ENF, SEV, DES, awRR, MAC.*	*Same*
Measuring Range	*CO_2: 0 to 25 vol%* *O_2: 0 to 100 vol%* *N_2O: 0 to 100 vol%* *HAL, ENF, ISO, SEV, DES: 0-25 vol%* *AwRR: 0 rpm to 150 rpm*	*CO_2: 0 to 25 vol%* *O_2: 0 to 100 vol%* *N_2O: 0 to 100 vol%* *HAL, ENF, ISO, SEV, DES: 0-25 vol%* *AwRR: 0 rpm to 150 rpm*	*Same*
Other Features			
WI-FI			
IEEE	*802. 11 b/g/n*	*802. 11 b/g/n*	*Same*
Frequency Band	*2.4 GHz ISM band*	*2.4 GHz ISM band*	*Same*
Power supply			
AC power			
Requirement	*100-240V~, 50/60Hz*	*100-240V~, 50/60Hz*	*Same*
Battery			
Rechargeable Battery	*Yes*	*Yes*	*Same*

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 LM-8, LM-10, LM-12 and LM-15 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. The tests performed are as follows:
Cytotoxicity
Skin Sensitization
Skin Irritation

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the LM-8, LM-10, LM-12 and LM-15 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 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 IEC 60601-1-2:2007. standard for EMC.

Table 2. Standards compliance

Standard	Conclusion
IEC 60601-1 IEC Medical electrical equipment - Part 1: General requirements for basic safety and essential performance ((2005) + Amd. 1 (2012)).	Pass
IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (Edition 4.0 2014).	Pass
IEC 60601-1-8 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. (Edition 2.1 2012).	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. Edition 3.0 2011-05.	Pass
IEC 62304 Medical device software – Software life cycle processes (2006 (First Edition) + A1:2015).	Pass
IEC 62366-1 Medical devices Part 1: Application of usability engineering to medical devices, including Amendment 1. (2015+AMD1:2020 (Consolidated Text)).	Pass
ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (3rd Edition 2010).	Pass
ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity. (3rd Edition 2010).	Pass
IEC 80601-2-30 Medical electrical equipment - Part 2-30: Particular requirements for basic safety and essential performance of automated type non-invasive sphygmomanometers. (Edition 2.0 2018).	Pass
ISO 80601-2-55 Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors. (2nd edition 2018).	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. (2nd edition 2017 [Including: Amendment 1-2018]).	Pass
ISO 80601-2-61 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment. (2nd edition 2017 - Corrected version 2018).	Pass
IEC 60601-2-49 Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment. (Ed. 2.0 b:2011).	Pass

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 tests were performed on the LM-8, LM-10, LM-12 and LM-15 monitors to validate their performance in terms of ECG, RESP, SpO2, NIBP, IBP, TEMP, Quick TEMP, C.O., CO2 and AG.

Summary

Based on the non-clinical and clinical performance as documented in the system development, the subject devices were found to be substantially equivalent to the predicate device.

Conclusion

The non-clinical data support the substantial equivalence of the device and the hardware and software verification and validation demonstrate that the LM-8, LM-10, LM-12 and LM-15 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 LM-8, LM-10, LM-12 and LM-15 Patient Monitor devices are substantially equivalent to the predicate devices.