August 1, 2022

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

Re: K221616
Trade/Device Name: Patient Monitor, models LMPLUS-12, LMPLUS-15 and LMPLUS-17
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, DRG, DPS
Dated: June 3, 2022
Received: June 3, 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 Kozen
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)*
K221616

Device Name
Patient Monitor, models LMPLUS 12, LMPLUS 15 and LMPLUS 17.

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

Patient Monitor, models LMPLUS-12, LMPLUS-15 and LMPLUS-17

June, 2022

ADMINISTRATIVE INFORMATION

Applicant

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Establishment Registration Number

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DEVICE AND CLASSIFICATION NAME

Device Trade Name: Patient Monitor, models LMPLUS-12, LMPLUS-15 and LMPLUS-17

Regulatory Class: Class II

Prior Submission: K160981

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 Device: K160981. Patient Monitor, models elite V5, elite V6 and elite V8. 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, 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.

Device Description

LMPLUS series Patient Monitor including LMPLUS-12, LMPLUS-15 and LMPLUS-17 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 LMPLUS 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 LMPLUS series Patient Monitor, the user may select different monitoring parameters in according with their requirements.

LMPLUS-12 configures with 12.1-inch color TFT touch screen, LMPLUS-15 and LMPLUS-17 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.

Contraindications:

There are no known contraindications for use.

Equivalence to Marketed Device

The LMPLUS series Patient Monitor is substantially equivalent to the predicate. 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

Feature	Subject Device	Predicate Device	Comparison
K #	Current submission	K160981	
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	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	Same

Feature	Subject Device	Predicate Device	Comparison
	(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.	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.	
Intended patient population	Adult, pediatric and neonatal patients	Adult, pediatric and neonatal patients	Same
Intended application environment	Hospital environment.	Hospital environment.	Same
1) 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 (x0.125), 2.5mm/mV (x0.25), 5mm/mV (x0.5), 10mm/mV (x1), 20mm/mV (x2), 40mm/mV (x4), AUTO gain	1.25mm/mV (x0.125), 2.5mm/mV (x0.25), 5mm/mV (x0.5), 10mm/mV (x1), 20mm/mV (x2), 40mm/mV (x4), AUTO gain	Same
Sweep	6.25mm/s, 12.5mm/s, 25mm/s, 50mm/s	6.25mm/s, 12.5mm/s, 25mm/s, 50mm/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

Feature	Subject Device	Predicate Device	Comparison
CMRR (Common Mode Rejection Ratio)	Diagnosis: >95dB Monitor: >105dB Surgery: >105dB	Diagnosis: >95dB Monitor: >105dB Surgery: >105dB	Same
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	Same
Differential Input Impedance	>5MΩ	>5MΩ	Same
Leakage Current of Patient	<10μA	<10μA	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 mV to +0.8 mV: ±0.02 mV or 10%, whichever is greater. Beyond this range: not specified.	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
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 mV to ±700 mV Width: 0.1 ms to 2.0 ms Ascending time: 10 μs 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% or 1 bpm, whichever is greater	Same
Resolution	1 bpm	1 bpm	Same
2) RESP monitor			
Principle of Operation	Thoracic impedance	Thoracic impedance	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
Measurement Range	Adult: 0 to 120 rpm Pediatric/neonate: 0 rpm to 150rpm	Adult: 0 to 120 rpm Pediatric/neonate: 0 rpm to 150rpm	Same

Feature	Subject Device	Predicate Device	Comparison
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
Calculation Type	Manual, Automatic	Manual, Automatic	Same
Baseline Impedance Range	200Ω to 2500Ω (with ECG cables of 1 KΩ resistance)	200Ω to 2500Ω (with ECG cables of 1 KΩ resistance)	Same
Measuring Sensitivity	Within the baseline impedance range: 0.3Ω	Within the baseline impedance range: 0.3Ω	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
Resolution	1 rpm	1 rpm	Same
Apnea Alarm	10s, 15s, 20s, 25s, 30s, 35s, 40s	10s, 15s, 20s, 25s, 30s, 35s, 40s	Same
3) Temperature monitor			
Technique	Thermal resistance	Thermal resistance	Same
Number of channels	2	2	Same
Measurement Range	0 to 50°C	0 to 50°C	Same
Accuracy	±0.1°C (±0.2°F)	±0.1°C (±0.2°F)	Same
Resolution	0.1°C	0.1°C	Same
4) SpO2 monitor			
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
5) PR			
Measurement Range	25 bpm to 300 bpm	25 bpm to 300 bpm	Same
Accuracy	±2bpm	±2bpm	Same
Resolution	1 bpm	1 bpm	Same
6) NIBP monitor			
Principle of Operation	Oscillation	Oscillation	Same
	Adult:	Adult:	Same

Feature	Subject Device	Predicate Device	Comparison
Measurement Range (mmHg)	Systolic 40 to 270 mmHg	Systolic 40 to 270 mmHg	Same
	Diastolic 10 to 215 mmHg	Diastolic 10 to 215 mmHg	Same
	Mean 20 to 235 mmHg	Mean 20 to 235 mmHg	Same
	Pediatric:	Pediatric:	Same
	Systolic 40 to 230 mmHg Diastolic 10 to 180 mmHg	Systolic 40 to 230 mmHg Diastolic 10 to 180 mmHg	Same
	Mean 20 to 195 mmHg	Mean 20 to 195 mmHg	Same
	Neonate:	Neonate:	Same
	Systolic 40 to 135 mmHg	Systolic 40 to 135 mmHg	Same
	Diastolic 10 to 100 mmHg	Diastolic 10 to 100 mmHg	Same
	Mean 20 to 110 mmHg	Mean 20 to 110 mmHg	Same
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 Pediatric: 245±3mmHg Pediatric: 147±3mmHg	Adult: 297±3mmHg Pediatric: 245±3mmHg Pediatric: 147±3mmHg	Same
Mode	Manual, Auto, Continuous	Manual, Auto, Continuous	Same
Measuring interval in AUTO Mode	1/2/3/4/5/10/15/30/60/90/120/240/ 480min	1/2/3/4/5/10/15/30/60/90/ 120/240/ 480min	Same
PR from NIBP			
Measurement Range	40 bpm to 240bpm	40 bpm to 240bpm	Same
Accuracy	±3bpm or 3.5%, whichever is greater	±3bpm or 3.5%, whichever is greater	Same
7) 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) 200 to 3000 Ω	Same
8) CO2 Monitor			
CO2 Module			
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

Feature	Subject Device	Predicate Device	Comparison
CO2 Measurement range	0 mmHg to 150 mmHg	0 mmHg to 150 mmHg	Same
AwRR Measurement range	2 rpm to 150 rpm	2 rpm to 150 rpm	Same
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.	**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.	Same
Resolution	1 mmHg	1 mmHg	Same
Sample flow rate	**EDAN:** 70ml/min or 100ml/min, optional (±15ml/min) **Respironics:**50 ±10 ml/min	**EDAN:** 70ml/min or 100ml/min, optional (±15ml/min) **Respironics:**50 ±10 ml/min	Same
Apnea Alarm Delay	10s, 15s, 20s, 25s, 30s, 35s, 40s.	10s, 15s, 20s, 25s, 30s, 35s, 40s.	Same
Respironics CAPNOSTAT 5 CO2 (Mainstream)			
Measure Parameters	$EtCO_2$, $FiCO_2$, AwRR	$EtCO_2$, $FiCO_2$, AwRR	Same
CO_2 Measurement range	0 mmHg to 150 mmHg	0 mmHg to 150 mmHg	Same
AwRR measurement range	0 rpm to 150 rpm	0 rpm 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	±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	Same
Resolution	1 mmHg	1 mmHg	Same

Feature	Subject Device		Predicate Device		Comparison
AwRR measurement accuracy	±1 rpm		±1 rpm		Same
9) C.O. Temperature					
Measurement method	Thermodilution method		Thermodilution method		Same
Measurement range	C.O.: 0.1 to 20L/min TB: 23 to 43°C TI: -1 to 27°C		C.O.: 0.1 to 20L/min TB: 23 to 43°C TI: -1 to 27°C		Same
Accuracy	C.O.: ±5% or ±0.2L/min, which is greater TB, TI: ±0.1°C (without sensor)		C.O.: ±5% or ±0.2L/min, which is greater TB, TI: ±0.1°C (without sensor)		Same
Resolution	C.O.: 0.1L/min TB, TI:0.1°C		C.O.: 0.1L/min TB, TI:0.1°C		Same
10) AG Monitor (Phasein and Drager)					
Technique	Infrared absorption		Infrared absorption		Same
Warm-uptime	Full accuracy mode: <20s(Phasein) Full accuracy mode: <450s(Drager)		Full accuracy mode: <20s(Phasein) Full accuracy mode: <450s(Drager)		Same
Sample flow rate	50±10ml/min(Phasein) 200 mL/min ±20 mL/min(Drager)		50±10ml/min(Phasein) 200 mL/min ±20 mL/min(Drager)		Same
Measurement Range and Accuracy	Range (%REL)	Accuracy (%ABS)	Range (%REL)	Accuracy (%ABS)	Same
	CO2		CO2		
	Phasein		Phasein		
	Sidestream: 0 to 15 vol% 15 to 25 vol% Mainstream: 0 to 10 vol% 10 to 15vol% 15 to 25 vol%	Sidestream: ± (0.2 vol% + 2% of reading) Unspecified Mainstream: ± (0.2 vol% + 2% of reading) ± (0.3 vol% + 2% of reading) Unspecified	Sidestream: 0 to 15 vol% 15 to 25 vol% Mainstream: 0 to 10 vol% 10 to 15vol% 15 to 25 vol%	Sidestream: ± (0.2 vol% + 2% of reading) Unspecified Mainstream: ± (0.2 vol% + 2% of reading) ± (0.3 vol% + 2% of reading) Unspecified	Same

Feature	Subject Device		Predicate Device		Comparison
	Drager		Drager		
	0 to 13.6 Vol%	± (0.43 Vol% + 8 % rel.)	0 to 13.6 Vol%	± (0.43 Vol% + 8 % rel.)	Same
	O_2		O_2		
	Phasein (Sidestream & Mainstream)		Phasein (Sidestream & Mainstream)		
	0 to 100 vol %	± (1 vol% + 2% of reading)	0 to 100 vol %	± (1 vol% + 2% of reading)	Same
	Drager		Drager		
	0 to 100 Vol%	± (2.5 Vol% + 2.5 % rel.)	0 to 100 Vol%	± (2.5 Vol% + 2.5 % rel.)	Same
	N_2O		N_2O		
	Phasein (Sidestream & Mainstream)		Phasein (Sidestream & Mainstream)		Same
	0 to 100 vol%	± (2 vol% + 2% of reading)	0 to 100 vol%	± (2 vol% + 2% of reading)	Same
	Drager		Drager		
	0 to 100 Vol%	± (2 Vol% + 8 % rel.)	0 to 100 Vol%	± (2 Vol% + 8 % rel.)	Same
	Des		Des		
	Phasein (Sidestream & Mainstream)				
	0 to 22 vol % 22 to 25 vol %	± (0.15 vol% + 5% of reading) Unspecified	0 to 22 vol % 22 to 25 vol %	± (0.15 vol% + 5% of reading) Unspecified	Same
	Drager		Drager		
	0 to 20 Vol%	± (0.2 Vol% + 15 % rel.)	0 to 20 Vol%	± (0.2 Vol% + 15 % rel.)	Same
	Sev		Sev		
	Phasein (Sidestream & Mainstream)				
	0 to 10 vol % 10 to 25 vol %	± (0.15 vol% + 5% of reading) Unspecified	0 to 10 vol % 10 to 25 vol %	± (0.15 vol% + 5% of reading) Unspecified	Same
	Drager		Drager		
	0 to 10 Vol%	± (0.2 Vol% + 15 % rel.)	0 to 10 Vol%	± (0.2 Vol% + 15 % rel.)	Same
	Enf		Enf		
	Phasein (Sidestream & Mainstream)				
	0 to 8 vol % 8 to 25 vol %	± (0.15 vol% + 5% of reading) Unspecified	0 to 8 vol % 8 to 25 vol %	± (0.15 vol% + 5% of reading) Unspecified	Same
	Drager		Drager		

Feature	Subject Device		Predicate Device		Comparison
	0 to 10 Vol%	± (0.2 Vol% + 15 % rel.)	0 to 10 Vol%	± (0.2 Vol% + 15 % rel.)	Same
	Iso		Iso		
	Phasein (Sidestream & Mainstream)				
	0 to 8 vol % 8 to 25 vol %	± (0.15 vol% + 5% of reading) Unspecified	0 to 8 vol % 8 to 25 vol %	± (0.15 vol% + 5% of reading) Unspecified	Same
	Drager		Drager		
	0 to 8.5 Vol%	± (0.2 Vol% + 15 % rel.)	0 to 8.5 Vol%	± (0.2 Vol% + 15 % rel.)	Same
	Hal		Hal		
	Phasein (Sidestream & Mainstream)				
	0 to 8 vol % 8 to 25 vol %	± (0.15 vol% + 5% of reading) Unspecified	0 to 8 vol % 8 to 25 vol %	± (0.15 vol% + 5% of reading) Unspecified	Same
	Drager		Drager		
	0 to 8.5 Vol%	± (0.2 Vol% +15 % rel.)	0 to 8.5 Vol%	± (0.2 Vol% +15 % rel.)	Same
11) BIS					
Technique	Bispectral index		Bispectral index		
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		6.25mm/s, 12.5mm/s, 25mm/s, 50mm/s		Same
Noise (EEG Waveform)	<0.3μV (0.25Hz~50Hz)		<0.3μV (0.25Hz~50Hz)		Same
EEG bandwidth	0.25Hz~50Hz		0.25Hz~50Hz		Same
12) RM					
Frequency response	>10Hz		>10Hz		Same
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: 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		Same
Accuracy	Adult: 0.5 L/min or ± 3% of reading, whichever is greater Pediatric:		Adult: 0.5 L/min or ± 3% of reading, whichever is greater Pediatric:		Same

Feature	Subject Device	Predicate Device	Comparison
	0.25 L/min or ± 3% of reading, whichever is greater Neonatal: 0.125 L/min or ± 3% of reading, whichever is greater	0.25 L/min or ± 3% of reading, whichever is greater Neonatal: 0.125 L/min or ± 3% of reading, whichever is greater	
Resolution	1.0 L/min	1.0 L/min	Same
Paw (or Airway Pressure)			
Measurement range	-120 cmH_2O to 120 cmH_2O	-120 cmH_2O to 120 cmH_2O	Same
Accuracy	0.5 cmH_2O or ± 2% of reading, whichever is greater	0.5 cmH_2O or ± 2% of reading, whichever is greater	Same
Resolution	1 cmH_2O	1 cmH_2O	Same
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: 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	Same
Accuracy	Adult: 0.1 L/min Pediatric: 0.1 L/min Neonatal: 0.1 L/min	Adult: 0.1 L/min Pediatric: 0.1 L/min Neonatal: 0.1 L/min	Same
TVe/TVi			
Measurement range	Adult: 40 mL to 2500 mL Pediatric: 6 mL to 750 mL Neonatal: 2 mL to 100 mL	Adult: 40 mL to 2500 mL Pediatric: 6 mL to 750 mL Neonatal: 2 mL to 100 mL	Same
Resolution	1.0 mL	1.0 mL	Same
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: ± 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	Same
12) RR (RM)			
Measurement range	Adult: 0 rpm to 120 rpm Pediatric/Neonate: 0 rpm to 150 rpm	Adult: 0 rpm to 120 rpm Pediatric/Neonate: 0 rpm to 150 rpm	Same
Accuracy	Adult: 6 to 120 rpm: ±2 rpm 0 to 5 rpm: not specified	Adult: 6 to 120 rpm: ±2 rpm 0 to 5 rpm: not specified	Same

Feature	Subject Device	Predicate Device	Comparison
	Pediatric/Neonate: 6 to 150 rpm: ±2 rpm 0 to 5 rpm: not specified	Pediatric/Neonate: 6 to 150 rpm: ±2 rpm 0 to 5 rpm: not specified	
Resolution	1 rpm	1 rpm	Same
Gain Selection	x0.25, x0.5, x1, x2, x3, x4, 5x5	x0.25, x0.5, x1, x2, x3, x4, 5x5	Same
Sweep	6.25 mm/s, 12.5 mm/s, 25mm/s, 50 mm/s	6.25 mm/s, 12.5 mm/s, 25mm/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
13) ICG			
Technique	Thoracic electrical bioimpedance	Thoracic electrical bioimpedance	Same
Measurement range	SV: 0 ml/beat~250 ml/beat HR: 40 bpm~250bpm C.O.: 0 L/min~30 L/min	SV: 0 ml/beat~250 ml/beat HR: 40 bpm~250bpm C.O.: 0 L/min~30 L/min	Same
Accuracy	SV: Undefined HR: ±2bpm C.O.: Undefined	SV: Undefined HR: ±2bpm C.O.: Undefined	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
Safety Classifications			
Type of protection against electric shock	Class I	Class I	Same
Ingress Protection	IPX1	IPX1	Same

Feature	Subject Device	Predicate Device	Comparison
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	BF	Same
CO_2, AG, BIS, RM, ICG	BF	BF	Same
Electrical & Mechanical safety & Thermal safety Standards			
General Standards	IEC 60601-1:2005	IEC 60601-1:2005	Same
EMC Standards	IEC 60601-1-2:2007	IEC 60601-1-2:2007	Same
Alarm Standards	IEC 60601-1-8:2006	IEC 60601-1-8:2006	Same
Biocompatibility Standards	ISO 10993-1:2009	ISO 10993-1:2009	Same
Software Standards	IEC 62304:2006	IEC 62304:2006	Same
Special Standards			
Basic safety and essential performance for patient monitor	IEC 60601-2-49: 2011	IEC 60601-2-49: 2011	Same
ECG	IEC 60601-2-27: 2011 IEC 60601-2-25: 2011	IEC 60601-2-27: 2011 IEC 60601-2-25: 2011	Same
NIBP	IEC 80601-2-30: 2009 ISO 81060-2	IEC 80601-2-30: 2009 ISO 81060-2	Same
IBP	IEC 60601-2-34: 2011	IEC 60601-2-34: 2011	Same
AG, CO2	ISO 80601-2-55	ISO 80601-2-55	Same
TEMP	ISO 80601-2-56 EN12470-4:2000	ISO 80601-2-56 EN12470-4:2000	Same
Power supply			
AC power			
Requirement	100-240V, 50/60Hz	100-240V, 50/60Hz	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	LMPLUS-12: <6.2kg LMPLUS-15: <7.5kg LMPLUS-17: <14kg	LMPLUS-12: <6.2kg LMPLUS-15: <7.5kg LMPLUS-17: <14kg	Same
Dimensions	LMPLUS-12: 333±2 mm (L) x 289±2 mm (H)x 211±2mm (W)	LMPLUS-12: 333±2 mm (L) x 289±2 mm (H)x 211±2mm (W)	Same

Feature	Subject Device	Predicate Device	Comparison
	LMPLUS-15: 384±2 mm (L) x 320±2 mm (H)x 213±2mm (W) LMPLUS-17: 425 mm (L) x 245 mm (W)x 382 mm (H)	LMPLUS-15: 384±2 mm (L) x 320±2 mm (H)x 213±2mm (W) LMPLUS-17: 425 mm (L) x 245 mm (W)x 382 mm (H)	
LCD	LMPLUS-12: 12.1 inches LCD LMPLUS-15: 15 inches LCD LMPLUS-17: 17 inches LCD	LMPLUS-12: 12.1 inches LCD LMPLUS-15: 15 inches LCD LMPLUS-17: 17 inches LCD	Same
LCD Resolution	LMPLUS-12: 800 x 600 LMPLUS-15: 1024 x 768 LMPLUS-17: 1280 x 1024	LMPLUS-12: 800 x 600 LMPLUS-15: 1024 x 768 LMPLUS-17: 1280 x 1024	Same
Environmental Specifications			
Temperature			
Working	+0°C to +40°C	+0°C to +40°C	Same
Transport and Storage	-20°C to +55°C	-20°C to +55°C	Same
Humidity			
Working	15% to 95% (non-condensing)	15% to 95% (non-condensing)	Same
Transport and Storage	15% to 95% (non-condensing)	15% to 95% (non-condensing)	Same
Altitude			
Working	860hPa to 1060hPa	860hPa to 1060hPa	Same
Transport and Storage	700hPa to 1060hPa	700hPa to 1060hPa	Same
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)	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

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 LMPLUS-12, LMPLUS-15 and LMPLUS-17 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 LMPLUS-12, LMPLUS-15 and LMPLUS-17 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.

Table 2 Standards compliance

Standards	Conclusion
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- Test report of elite LMPLUS 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 LMPLUS 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 LMPLUS 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 LMPLUS 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 LMPLUS 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 LMPLUS 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 LMPLUS 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 LMPLUS 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 LMPLUS series	Pass
IEC62366 - Medical devices - Application of usability engineering to	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 LMPLUS 12, LMPLUS 15 and LMPLUS 17 monitors to validate their performance in terms of noninvasive blood pressure (NIBP) and SpO2 accuracy.

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.

Conclusion

The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that the LMPLUS-12, LMPLUS-15 and LMPLUS-17 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 LMPLUS-12, LMPLUS-15 and LMPLUS-17 Patient Monitor devices are substantially equivalent to the predicate devices.