December 31, 2019

Shenzhen Creative Industry Co., Ltd.
℅ Charlie Mack
Principal Engineer
IRC
2950 E Lindrick Drive
Chandler, Arizona 85249

Re: K192343
Trade/Device Name: Patient Monitor, Models K10, K12 and K15
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN, DQA, CCK, FLL, MWI
Dated: November 17, 2019
Received: November 26, 2019

Dear Charlie Mack:

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,

for
Stephen Browning
Acting Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192343

Device Name
Patient Monitor, Models K10, K12, K15

Indications for Use *(Describe)*
This Patient Monitor is a multi-functional instrument designed for monitoring the vital physiological signs of adult and pediatric (but not neonatal) patients. With the functions of real-time recording and displaying parameters, such as ECG, heart rate(HR), non-invasive blood pressure (NIBP), functional oxygen saturation (SpO2), respiration rate (RESP), body temperature (TEMP), end-tidal CO2 concentration (EtCO2), it allows comprehensive analysis of patient's physiological conditions.

This instrument is applicable for use in hospitals and clinical institutions. The operation should be performed by qualified professionals only.

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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Shenzhen Creative Industry Co., Ltd.

510(k) Summary (21 CFR §807.92)

Submitter Information:

Submitter Name:	Shenzhen Creative Industry Co., Ltd.
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Contact Person:	Ms. Jia Wang General Manager
Email:	charliemack@irc-us.com

Date of Preparation: December 26, 2019

Subject Devices :

Trade/proprietary name: Patient Monitor, Models K10, K12, K15

Common Name: Patient Monitor

Classification :

Function	Product Code	CFR	Panel
SpO_2	DQA	870.2700	Anesthesiology
CO_2	CCK	868.1400	Anesthesiology
ECG/RESP	MWI	870.2300	Cardiovascular
NIBP	DXN	870.1130	Cardiovascular
TEMP	FLL	880.2910	General Hospital

Predicate Devices :

Trade Name: UP-7000 Patient Monitor

510(k) Reference: K123711

Common Name: Patient Monitor

Regulation Number:

Function	Product Code	CFR	Panel
SpO_2	DQA	870.2700	Anesthesiology
CO_2	CCK	868.1400	Anesthesiology
ECG/RESP	MWI	870.2300	Cardiovascular
NIBP	DXN	870.1130	Cardiovascular
TEMP	FLL	880.2910	General Hospital

Regulatory Class: Class II

Manufacturer: Shenzhen Creative Industry Co., LTD.

Purpose of Submission

This is a new traditional 510(K) submission of Patient Monitor, Models K10, K12, K15.

Device Description

Overview

This Patient Monitor is a multi-functional instrument designed for monitoring the vital physiological signs of adult and pediatric (not neonatal) patients. With the functions of real-time recording and displaying parameters, such as ECG, pulse rate (PR), non-invasive blood pressure (NIBP), functional oxygen saturation (SpO_2), respiration rate (RESP), body temperature (TEMP), end-tidal CO_2 concentration ($EtCO_2$), it allows comprehensive analysis of patient's physiological conditions.

This instrument is applicable for use in hospitals and clinical institutions. The operation should be performed by qualified professionals only.

There are three versions of the K serial Patient Monitor, K10, K12 and K15. The primary difference is physical dimension and display TFT size; all other specifications remain unchanged. All versions have the same indications for use.

Features

This monitoring system may be used to monitor a patient's physical parameters as followed: End-tidal Carbon Dioxide ($EtCO_2$), Forced inspiratory carbon dioxide ($FiCO_2$), ECG, heart rate, non-invasive blood pressure (NIBP), Respiratory Rate(RR), body temperature(TEMP), Pulse Oxygen Saturation (SpO_2) and Pulse Rate(PR).

- It can measure SpO_2, Pulse Rate, and Perfusion Index displays on the LCD.
- It can measure End-tidal CO_2 ($EtCO_2$), $FiCO_2$, and Respiration Rate. The CO_2 waveform displays on the LCD.
- It can measure ECG, heart rate, and Respiration Rate(RR). Which enables simultaneous monitoring of several ECG waveforms and display on the LCD.
- It can measure non-invasive blood pressure(NIBP) and body temperature(TEMP); the measured value can be displayed on LCD.

- Real-time monitoring of battery capacity, when the battery power is insufficient, low battery voltage alarm indication displays on the LCD screen.
- The customer could use either mainstream or sidestream for the same monitor.
- Two operating modes: normal monitoring and power-saving mode.
- Flexible menu setup and audible/visual alarm function.
- It is battery powered and can also be powered by an AC mains power supply.
- The built-in printer is optional.

Indication for use

This Patient Monitor is a multi-functional instrument designed for monitoring the vital physiological signs of adult, pediatric (but not neonatal) patients. With the functions of real-time recording and displaying parameters, such as ECG, Heart rate (HR), non-invasive blood pressure (NIBP), functional oxygen saturation (SpO2), respiration rate (RESP), body temperature (TEMP), end-tidal CO2 concentration (EtCO2), it allows comprehensive analysis of patient's physiological conditions.

This instrument is applicable for use in hospitals and clinical institutions. The operation should be performed by qualified professionals only.

Comparison with the predicate device:

Shenzhen Creative Industry Co., Ltd. believes that the Shenzhen Creative Industry Co., Ltd. Patient Monitor, Models K10, K12, K15 is substantially equivalent to the Shenzhen Creative Industry UP-7000 Patient Monitor (K123711). General Specifications (physical/electrical and operational properties) Remark: For the subject K serial Patient Monitor, there are three variations K10, K12, K15; The primary is physical dimension and display TFT size, all other specification remain unchanged. They have the same indications for use. The minor differences in the technological characteristics do not raise issues of safety and effectiveness.The subject device is identical to the predicate device. Please refer to the following pages for specific difference details.

Comparison to Predicate Devices

Characteristics	Submitted Device	Predicate Device	Difference Discussion
Physical dimension(mm) /weight(kg)	K10: 295mm(L)x178mm(D) x334mm(H)/4.5kg K12: 313mm(L)x178mm(D) x334mm(H)/5.2kg K15: 357mm(L)x178mm(D) x334mm(H)/5.7kg	300 (L) x150 (D) x290 (H)/ 5.2kg	The physical dimension difference does not raise any new questions of safety and effectiveness.
Display	K15: 26.4cm(15") TFT K12: 30.7cm(12.1") TFT K10: 26.4cm(10.4") TFT	12.1” Color TFT	The display dimension difference does not raise any new questions of safety and effectiveness.
Type, Degree of protection against electric shock	Class I with internal electric power supply. Where the integrity of the external protective earth(ground) in the installation or its conductors is in doubt, the equipment shall be operated from its internal electric power supply(batteries) CO_2: BF(defibrillation proof) ECG/RESP/TEMP/SPO_2 /NIBP:CF(defibrillation proof)	Class I with internal electric power supply. Where the integrity of the external protective earth(ground) in the installation or its conductors is in doubt, the equipment shall be operated from its internal electric power supply(batteries) CO_2: BF(defibrillation proof) ECG/RESP/TEMP/SPO_2 /NIBP:CF(defibrillation proof)	Identical
Power supply	Battery or AC	Battery or AC	Identical
AC Power Supply	100~240V 50/60Hz 65VA	100~240V 50/60Hz 100VA	The subject devices are powered by an external adapter and lithium battery which full match the design requirement and complying the applicable standards, including IEC60601-1, IEC60601-1-2, and IEC62133
Internal power source	Rechargeable Sealed Li-ion battery 11.1V 4.4AH	Rechargeable sealed lead-acid battery, 12V 2.3AH	The subject devices are powered by an external adapter and lithium battery which full match the design requirement and complying the applicable standards, including IEC60601-1, IEC60601-1-2, and IEC62133

Characteristics	Submitted Device	Predicate Device	Difference Discussion
Battery charging indicator	Yes	Yes	Identical
Low battery indicator	Yes	Yes	Identical
Battery charge time, typical	Maximum 13~15 hours for charging	Maximum 13~15 hours for charging	Identical
Flammable anesthetics	N/A	N/A	Identical
Operating condition	Temperature: 5℃—40℃; Humidity: 30%—80%,non-condensing Atmospheric pressure: 70kPa—106.0kPa	Temperature: 5℃—40℃; Humidity: 30%—80%,non-condensing Atmospheric pressure: 70kPa—106.0kPa	Identical
Storage condition	Temperature: -20℃—60℃; Humidity: 10%—95%,non-condensing atmosphere: 53kPa—106kPa	Temperature: -20℃—60℃; Humidity: 10%—95%,noncondensing atmosphere: 53kPa—106kPa	Identical
EMC	The equipment meets the requirements of IEC 60601-1-2:2014	The equipment meets the requirements of IEC 60601-1-2:2007	Identical
Power-on self-test	Yes	Yes	Identical
Optional printer	Yes	Yes	Identical

2. SPO_2 - Same as in Predicate Device

Characteristics	Submitted Device	Predicate Device	Difference Discussion
Name and model	Patient Monitor, Models K10, K12, K15	UP-7000 Patient Monitor	N/A
Manufacturer	Shenzhen Creative Industry Co., Ltd.	Shenzhen Creative Industry Co., Ltd.	N/A
510(K) Number:	N/A	K123711	N/A
SPO_2 module	Creative SPO_2 module【KM-SPO-03(AFE)】with the same principle as UP-7000(K123711)Creative SPO_2 sensor only	Creative SPO_2 module【KM-SPO-03(AFE)】with the same principle as PC-60(K063641)Creative SPO_2 sensor only	No change
Patient type	Adult, pediatric (but not neonatal) patients	Adult, pediatric patients	No change
SPO_2 display range	0%~100%	0%~100%	No change
SPO_2 measurement accuracy	Adult and Pediatric (but not neonatal): ±3% (during 70%~100%) Undefined (during 0~70%)	Adult and Pediatric: ±3% (during 70%~100%) Undefined (during 0~70%)	No change
Alarm range (%)	High Limit: 1%~100% Lower Limit. 0%~99%	High Limit: 1%~100% Lower Limit. 0%~99%	No change
Pulse rate measurement range	30 bpm~240 bpm	30 bpm~240 bpm	No change
Pulse rate accuracy	±2bpm or ±2% (whichever is greater)	±2bpm or ±2% (whichever is greater)	No change
Alarm range–Pulse rate (bpm)	High Limit: 1bpm~300bpm Lower Limit. 0bpm~299bpm	High Limit: 1bpm~300bpm Lower Limit. 0bpm~299bpm	No change

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3. CO_2 - Same as in Predicate Device

Characteristics	Submitted Device	Predicate Device	Difference Discussion
Name and model	Patient Monitor, Models K10, K12, K15	UP-7000 Patient Monitor	N/A
Manufacturer	Shenzhen Creative Industry Co., Ltd.	Shenzhen Creative Industry Co., Ltd.	N/A
510(K) Number:	N/A	K123711	N/A
CO_2 module	Respironics LoFloTM $EtCO_2$ (Side-stream) Module(K053174) and CAPNOSTAT 5 $EtCO_2$ (Main-stream) Module(K042601)	Respironics LoFloTM $EtCO_2$ (Side-stream) Module(K053174) and CAPNOSTAT 5 $EtCO_2$ (Main-stream) Module(K042601)	No change
CO_2 measurement method	Infrared absorption method	Infrared absorption method	No change
CO_2 measure mode	Sidestream or Mainstream	Sidestream or Mainstream	No change
Measuring parameters	$EtCO_2$, $FiCO_2$ and Respiration Rate	$EtCO_2$, $FiCO_2$ and Respiration Rate	No change
CO_2 Response Time	Sidestream: <3seconds (includes transport time and rise time). Mainstream: <60ms (rise time)	Sidestream: <3seconds (includes transport time and rise time). Mainstream: <60ms (rise time)	No change
Units	mmHg, kPa or Vol%	mmHg, kPa or Vol%	No change
CO_2 measure range	$EtCO_2$: 0~150mmHg $FiCO_2$: 3~50mmHg	$EtCO_2$: 0~150mmHg $FiCO_2$: 3~50mmHg	No change
CO_2 Resolution	0.1mmHg (0~69mmHg) 0.25mmHg (70~150mmHg)	0.1mmHg (0~69mmHg) 0.25mmHg (70~150mmHg)	No change
CO_2 Accuracy	0~40 mmHg ±2mmHg 41~70 mmHg ±5% of reading 71~100 mmHg ±8% of reading 101~150mmHg±10% of reading	0~40 mmHg ±2mmHg 41~70 mmHg ±5% of reading 71~100 mmHg ±8% of reading 101~150mmHg±10% of reading	No change
Respiration Rate measure range	2~150rpm (Sidestream) or 0~150rpm (Mainstream)	2~150rpm (Sidestream) or 0~150rpm (Mainstream)	No change
Respiration Rate resolution	1rpm	1rpm	No change
Respiration Rate accuracy	±2rpm	±2rpm	No change
Flow Rate	50ml/min ±10 ml/min (Sidestream)	50ml/min ±10 ml/min (Sidestream)	No change
No Breath Alarm Delay	10~60s	10~60s	No change
Alarm adjustment range of $EtCO_2$	High Limit: 1mmHg~160mmHg Lower Limit. 0mmHg~159mmHg	High Limit: 1mmHg~160mmHg Lower Limit. 0mmHg~159mmHg	No change
Alarm adjustment range of RR	High Limit: 1bpm~150bpm Lower Limit. 0bpm~149bpm	High Limit: 1bpm~150bpm Lower Limit. 0bpm~149bpm	No change

4. ECG – Same as in Predicate Device

Characteristics	Submitted Device	Predicate Device	Difference Discussion
Name and model	Patient Monitor, Models K10, K12, K15	UP-7000 Patient Monitor	N/A
Manufacturer	Shenzhen Creative Industry Co., Ltd.	Shenzhen Creative Industry Co., Ltd.	N/A
510(K) Number:	N/A	K123711	N/A
ECG Module	Creative ECG/RESP module; ECG Cable cleared under K082959 of UNIMED MEDICAL SUPPLIES INC.	Creative ECG/RESP module; ECG Cable cleared under K082959 of UNIMED MEDICAL SUPPLIES INC.	No change
Lead	AHA, EURO	AHA, EURO	No change
Lead option	Yes	Yes	No change
Gain	2.5mm/mV(×0.25) 5mm/mV(×0.5), 10mm/mV(×1), 20mm/mV(×2) ,40 mm/mV(×4)and AUTO	2.5mm/mV(×0.25) 5mm/mV(×0.5), 10mm/mV(×1), 20mm/mV(×2) ,40 mm/mV(×4)and AUTO	No change
Sweep speed	6.25mm/s ,12.5mm/s, 25mm/s, 50mm/s	12.5mm/s, 25mm/s, 50mm/s	Similar
Range of heart rate monitoring	15 bpm ~ 350 bpm	15 bpm ~ 350 bpm	No change
Resolution	1bpm	1bpm	No change
Precision	±1% or ± 2 bpm, whichever is greater.	±1% or ± 2 bpm, whichever is greater.	No change
Alarm setting	Adult high Limit: (1~350) bpm Adult low Limit: (0~349) bpm Pediatric (but not neonatal) high Limit: (1~350) bpm Pediatric (but not neonatal) low Limit: (0~349) bpm	Adult high Limit: (1~350) bpm Adult low Limit: (0~349) bpm Pediatric high Limit: (1~350) bpm Pediatric low Limit: (0~349) bpm	No change
Input resistance	2: 10MO(differential)	2: 5MO(single ended)	Similar
CMRR	Diagnostic mode: 2: 90dB Monitor mode: 2: 105dB Operation mode: 2: 105dB	Diagnostic mode: 2: 90dB Monitor mode: 2: 105dB Operation mode: 2: 105dB	No change

Characteristics	Submitted Device	Predicate Device	Difference Discussion
Anti-polarized voltage	+/-300mV	+/-300mV	No change
ECG mode	Monitoring, Diagnostic, Operation	Monitoring, Diagnostic	Added one “Operation” mode, and the difference does not raise any new questions of safety and effectiveness and still complies with the IEC 60601-2-27 requirement same as Predicate device.
Frequency characteristic	Monitoring mode: 0.67Hz—40 Hz Diagnostic mode: 0.05 Hz—75 Hz Operation mode:1Hz—20Hz	Monitoring mode: 0.5 Hz—40 Hz Diagnostic mode: 0.05 Hz—75 Hz	A little difference in frequency characteristic but it does not raise any new questions of safety and effectiveness and still complies with the IEC 60601-2-27 requirement same as Predicate device.
Safeguard	CF	CF	No change

5. RESP – Same as in Predicate Device

Characteristics	Submitted Device	Predicate Device	Difference Discussion
Name and model	Patient Monitor, Models K10, K12, K15	UP-7000 Patient Monitor	N/A
Manufacturer	Shenzhen Creative Industry Co., Ltd.	Shenzhen Creative Industry Co., Ltd.	N/A
510(K) Number:	N/A	K123711	N/A
RESP Module	Creative ECG/RESP module; ECG Cable cleared under K082959 of UNIMED MEDICAL SUPPLIES INC.	Creative ECG/RESP module; ECG Cable cleared under K082959 of UNIMED MEDICAL SUPPLIES INC.	No change
Lead	Optional: lead I and lead II; default lead II	Optional: lead I and lead II; default lead II	No change
Measurement technique	Thoracic impedance	Thoracic impedance	No change
Sweep speed	6.25mm/s,12.5mm/s,	6.25mm/s,12.5mm/s,	No change
Respiration excitation Waveform	<300uA, sinusoid, 75kHz (±10%)	<300uA, sinusoid, 75kHz (±10%)	No change
Respiration impedance test Range	0.3 to 3 O	0.3 to 3 O	No change
Baseline impedance range	200 to 2500O(using an ECG cable with 1kO resistance)	200 to 2500O(using an ECG cable with 1kO resistance)	No change
Differential input impedance	>2.5 MO	>2.5 MO	No change
Linear Signal Range	3O p-p minimum	3O p-p minimum	No change
Bandwidth	0.2 to 2Hz(-3 dB)	0.2 to 2Hz(-3 dB)	No change
RESP rate measuring range	0rpm~120rpm	0rpm~120rpm	No change
RESP rate accuracy	±2% or ±2 rpm, whichever is greater	±2% or ±2 rpm, whichever is greater	No change

6. NIBP – New NIBP Module

Characteristics	Subject Device	Predicate Device	Difference Discussion
Name and model	Patient Monitor, Models K10, K12, K15	UP-7000 Patient Monitor	N/A
Manufacturer	Shenzhen Creative Industry Co., Ltd.	Shenzhen Creative Industry Co., Ltd.	N/A
510(K) Number:	N/A	K123711	N/A
NIBP module	KM-NIBP-12V02/SMD	SunTech Advantage 2.0 NIBP Module	The new NIBP module used in subject devices complies with the same IEC80601-2-30 standards and design requirement as Predicate device.
Method	Oscillometric method	Oscillometric method	Identical
Patient type	Adult and Pediatric (not neonatal):patients	pediatric and adult patients	Identical
Unit of measure	mmHg & kPa	mmHg & kPa	Identical
Pressure measurement range – Systolic	Adult: 40 ~ pediatric (not neonatal):: 40 ~ 200mmHg	Adult: 40 ~ 260mmHg pediatric: 40 ~ 160mmHg	The new NIBP module used in subject devices has little difference in measurement range, but still complying with the same IEC80601-2-30 standards and design requirement as Predicate device.
Pressure measurement range – Diastolic	Adult: 10 ~ 210mmHg pediatric (not neonatal):: 10 ~ 150mmHg	Adult: 20 ~ 200mmHg pediatric: 20 ~ 120mmHg	The new NIBP module used in subject devices has little difference in measurement range, but still complying with the same IEC80601-2-30 standards and design requirement as Predicate device.

Characteristics	Subject Device	Predicate Device	Difference Discussion
Pressure measurement range-Mean pressure	Adult: 20 ~ 230 mmHg pediatric (not neonatal):: 20 ~ 165mmHg	Adult: 26 ~ 220mmHg pediatric: 26 ~ 133mmHg	The new NIBP module used in subject devices has little difference in measurement range, but still complying with the same IEC80601-2-30 standards and design requirement as Predicate device.
BP accuracy	Max. mean deviation values:±5 mmHg; Max. standard deviation: 8 mmHg.	mean deviation values:±5 mmHg; Standard deviation: <= 8 mmHg.	Identical
Standard compliance	IEC/ISO 80601-2-30:2009+A1:2013 ANSI/AAMI/ISO 81060-2:2009	Meets ANSI/AAMI SP10:2002, EN1060-4:2004	The new NIBP module complies with the new FDA recognized standards.
Cuff pressure range	0 to 300mmHg	0 to 300mmHg	Identical
Overpressure protector	Internal operating software ensures that:- ❖ Maximum cuff inflation time is limited to 50 seconds (Adult mode), 35 seconds (Pediatric (not neonatal):mode) ❖ Duration of blood pressure reading is limited to 120 seconds (Adult mode), 90 seconds (Pediatric (not neonatal): mode) Additional redundant safety circuitry oversees the normal operation and overrides to abort a reading if: cuff pressure exceeds 300mmHg (Adult mode) or 240mmHg (Pediatric (not neonatal):mode) at any time. The cuff has been inflated for 180 seconds (Adult & Pediatric (notneonatal):modes)	Internal operating software ensures that:-- ❖ Maximum cuff inflation time is limited to 75 seconds ❖ Duration of blood pressure reading is limited to 130 seconds (Adult mode), 90 seconds (Pediatric mode) Additional redundant safety circuitry oversees the normal operation and overrides to abort a reading if: ❖ Cuff pressure exceeds 300mmHg (Adult & Pediatric modes)at any time. ❖ The cuff has been inflated for 180 seconds (Adult & Pediatric modes).	The Maximum cuff inflation time (Adult mode) of the subject device is shorter than the Predicate device. The blood pressure reading time (adult mode) is shorter than the Predicate device. The difference does not raise any new questions of safety and effectiveness.

Characteristics			Subject Device	Predicate Device	Difference Discussion
Alarm setup	Systolic	High Limit	Adult: 30~280 mmHg Pediatric (not neonatal): 30~200 mmHg	Adult: 31~280 mmHg Pediatric: 30~200 mmHg	Similar
		Lower Limit	Adult: 29~279 mmHg Pediatric (not neonatal):: 29~199 mmHg	Adult: 29~279 mmHg Pediatric: 29~199 mmHg	Identical
	Diastolic	High Limit	Adult : 11~232 mmHg Pediatric (not neonatal):: 11~150 mmHg	Adult : 11~232 mmHg Pediatric: 11~150 mmHg	Identical
		Lower Limit	Adult : 10~231 mmHg Pediatric (not neonatal):: 10~149 mmHg	Adult : 10~231 mmHg Pediatric: 10~149 mmHg	Identical
Alarm method			Sound light alarm , and record the alarm status for review	Sound light alarm , and record the alarm status for review	Identical

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7. TEMP – New TEMP Module

Characteristics	Subject Device	Predicate Device	Difference Discussion
Name and model	Patient Monitor, Models K10, K12, K15	UP-7000 Patient Monitor	N/A
Manufacturer	Shenzhen Creative Industry Co., Ltd.	Shenzhen Creative Industry Co., Ltd.	N/A
510(K) Number:	N/A	K123711	N/A
TEMP Module	KRK-TEMP PCBA 601S-E3	Clinical electronic Thermometers (K982140)	The new TEMP module used in subject devices complies with the same ISO80601-2-56 standards and design requirement as Predicate device.
Measurement means	Thermo-resistor type	Thermo-resistor type	Identical
Patient type	Adult , Pediatric (not neonatal):	Adult, Pediatric	Identical
Unit of measure	℃ or ℉	℃ or ℉	Identical
Measurement site	Body surface	Body surface	Identical
Temperature measurement range	21.0℃ to 50.0℃ (69.8℉ to 122℉)	32.0℃ to 43.9℃ (90℉ to 109.9℉)	The difference in measurement range does not raise any new questions of safety and effectiveness and still complies with the ISO80601-2-56 requirement same as Predicate device.
Temperature measurement accuracy	±0.2℃(25.0℃ to 45.0℃) ±0.4℃ for the rest of the range	±0.1℃(35.0℃ to 39.0℃) ±0.2℉(95.0℉ to 102.2℉) ±0.2℃ the rest	The difference in measurement accuracy does not raise any new questions of safety and effectiveness and still complies with the ISO80601-2-56 requirement same as Predicate device.

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Safety and Performance Data :

To establish substantial equivalence to the identified predicate devices, tests were completed as defined below to the subject devices, Patient Monitor, Models K10, K12, K15. The results of the testing demonstrate that the devices comply with the applicable standards requirements, and the devices are substantially equivalent to the predicate devices.

Non-Clinical Study:

Safety and EMC

- *IEC 60601-1: 2005+A1: 2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
- *IEC 60601-1-2: 2014 Medical devices part 1-2: General requirements for basic safety and essential performance – Collateral standards: electromagnetic compatibility – Test and requirements*

Performance Data:

- *IEC 60601-2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment (2011)*
- *ISO 80601-2-61 Second Edition 2017-12, medical electrical equipment - part 2-61: particular requirements for basic safety and essential performance of pulse oximeter equipment. (Anesthesiology)*
- *ISO 80601-2-55 First edition 2011-12-15 Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*
- *IEC 60601-2-27 Medical Electrical Equipment - Part 2-27: Particular Requirements For The Basic Safety And Essential Performance Of Electrocardiographic Monitoring Equipment [Including Corrigendum 1 (2012)]*
- *ANSI AAMI EC53:2013 ECG trunk cables and patient lead wires*
- *IEC 80601-2-30 Edition 1.1 2013-07 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers*
- *ISO 81060-2 Second edition 2013-05-01 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type*
- *ISO 80601-2-56 Second edition 2017-03 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.*
- *IEC 60601-1-8 Edition 2.1 2012-11 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*

Biocompatibility

- *ISO 10993-5: 2009 Biological evaluation of medical devices – Part 5 Tests for In Vitro Cytotoxicity*
- *ISO10993-10: 2010 Biological evaluation of medical Devices – Part 10: Tests for Irritation and Delayed-Type Hypersensitivity*
- *The subject device is classified as a surface device and contact (hand, chest) for a limited duration.*

Clinical Study:

- *ISO 81060-2 Second edition 2013-05-01 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type*

Conclusion:

The differences between subject devices and predicate device do not raise issues of safety and effectiveness based on the indication for use, technological characteristics, and performance testing. The subject device complies with the same applicable standards as the predicate device.

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, the subject device, Patient Monitor, K10, K12, K15 is safe and effective and substantially equivalent to predicate devices as described herein

END