DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 9, 2017

Shenzhen Creative Industry Co., Ltd.
% Mr. Charles Mack
Principal Engineer
IRC, LLC
7808 Rush Creek Drive
Pasco, Washington 99301

Re: K170047
Trade/Device Name: All-in-One Health Monitor, PC-303
Regulation Number: 21 CFR 870.2300
Regulation Name: Physiological Patient Monitor (Without Arrhythmia Detection Or Alarms)
Regulatory Class: Class II
Product Code: MWI, DQA, DXN, FLL, NBW, DSH
Dated: July 22, 2017
Received: August 1, 2017

Dear Mr. Charles 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. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170047

Device Name
All-in-One Health Monitor, PC-303

Indications for Use *(Describe)*

The All-in-One Health Monitor PC-303 is a device designed for spot-checking measuring of the patient's physiological parameters, such as Non-Invasive Blood Pressure (NIBP), Oxygen saturation (SpO2), Pulse Rate (PR) and Body Temperature (TEMP);

Additionally, the device is available to communicate with the compatible Blood Glucose Monitoring System and ECG monitor to make the measurement.

This device is applicable for Adult and Pediatric (age≥3 years old) use in clinical institutions and has no conditions or factors of contraindication.

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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: April14, 2017

1. **Company and Correspondent making the submission:**

Name – Shenzhen Creative Industry Co., Ltd.
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Contact – Mrs. Jia Wang
General Manager

US Agent and Correspondent
Mr. Charles Mack
PRINCIPAL ENGINEER
IRC USA
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Tel: 931-6254938
Email: charliemack@irc-us.com

2. Device :

Trade/proprietary name:	All-in-One Health Monitor, PC-303
Common Name:	Patient Monitor
Classification Name:	Monitor, Physiological, Patient (without arrhythmia detection or alarms)
Classification ProCode:	MWI
Device Class:	II
Regulation Number:	870.2300
Other ProCodes:	DQA, Oximeter DXN, System Mearurement, Blood Pressure, non-invasive FLL, Thermometer, electronic, clinical NBW, System, test, blood glucose OTC DSH, Recorder, magnetic tape for ECG

3. Predicate Devices :

Manufacturer	PredicateDevice	510(k) Number	SubmittedDevice
Shenzhen Creative Industry Co., Ltd	UP-7000 Patient Monitor	K123711	All-in-One Health Monitor, PC-303

4. Classifications Names & Citations :

Primary: MWI, monitor,physiological,patient(without arrhythmia detection or alarms)

Secondary: DQA, SpO2 Pulse Rate; DXN, NIBP; FLL, Temperature; NBW, Blood Glucose; DSH, ECG

5. Device Description:

Device Description:
The All-in-One Health Monitor, PC-303 is mobile modular designed patient monitor. It monitors the patient's blood oxygen saturation (SpO2) and pulse rate (PR) non-invasively by the photoelectric method. It can also measure non-invasive blood pressure (NIBP, the pressures of systolic, diastolic and mean) by the oscillating method and body temperature (TEMP) by the infrared radiation energy technology.

Additionally, the device is also capable to link and communicate with the compatible Blood Glucose Meter and ECG monitor to make the measurement.

This device system measure the patient's physical parameters with variety modules. It takes digital signals from NIBP, SpO2, Temperature module through COM ports, and receives ECG data, blood glucose data from compatible legally marketed ECG Monitor or BLOOD GLUCOSE MONITORING Device. The software to process the data, then display parameters on the screen and storage some useful information.

This device is applicable for use in clinical institutions and has no conditions or factors of contraindication.

Device Features:
This monitoring system may be used to monitor up to 10 of a patient's physical parameters such as Pulse Oxygen Saturation (SpO2), Pulse Rate; Non-invasive blood pressure (NIBP); Body temperature (TEMP); ECG, heart rate and BLOOD GLUCOSE:

- Large numeric display, segmented LCD panel, real-time clock display. Blood pressure measurements can be activated or canceled by one shortcut button.
- Oximetry technique displays SpO2 & pulse rate measurements by smart sensors.

- Smart infrared temperature probe presents measurements of body temperature.
- Blood pressure, oxygen saturation, pulse rate and temperature can be measured simultaneously.
- Blood Glucose meter option can be connected to the device.
- The Easy ECG Monitor option can be connected to the device.
- Data storage with recall, up to 999 groups of records can be stored and recognized by patient ID.
- Power management with power saving mode, auto power off and low battery indicator;

Below is a brief tabular display of the monitor functions and operations.

	Function	Product Code	Module 510K Status
Built-in Function:			
Built-in	SpO2 Pulse Rate	DQA	Creative SpO_2 sensor only (K063641)
Built-in	NIBP	DXN	Creative B01-WK126 NIBP Module
Built-in	TEMP	FLL	Valeo VT-601E IR Ear thermometer (K111463)
External Linked Function (Optional):			
External Linked Function	Blood Glucose	NBW	G-777G BLOOD GLUCOSE MONITORING SYSTEM (K113077)
External Linked Function	ECG	DSH	PC-80 Easy ECG Monitor (K073152)

6. Indication for use:

The All-in-One Health Monitor, PC-303 is a device designed for spot-checking measuring of the patient's physiological parameters, such as Non-Invasive Blood Pressure (NIBP), Oxygen saturation (SpO2), Pulse Rate (PR) and Body Temperature (TEMP);

Additionally, the device is available to communicate with the compatible Blood Glucose Monitoring System and ECG monitor to make the measurement.

This device is applicable for Adult and Pediatric (age≥3 years old) use in clinical institutions and has no conditions or factors of contraindication.

7. Comparison with predicate device:

Shenzhen Creative Industry Co., Ltd. believes that the All-in-One Health Monitor, PC-303 is substantially equivalent to the (K123711) Patient Monitor (Shenzhen Creative Industry Co., Ltd.).

Table of Comparison to Predicate Device
General Specifications

Characteristics	Subject Device	Predicate Device
Name and model	All-in-One Health Monitor, PC-303	UP-7000 Patient Monitor
510K Applicant	Shenzhen Creative Industry Co., LTD.	Shenzhen Creative Industry Co., LTD.
510(K) Number	N/A	K123711
Physical dimension(mm) /weight(kg)	165(L) X 96(W) X 68(H)/ 0.44kg	300 (L) x150 (W) x290 (H)/ 5.2kg
Display	4.3" Segment LCD	12.1" Color TFT
Type, Degree of protection against electric shock	Class II with internal electric power supply. SpO2/NIBP/TEMP: Type BF applied part.	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) CO2: BF (defibrillation proof) SpO2/NIBP /TEMP/ECG/RESP: CF (defibrillation proof)
Power supply	Battery or AC	Battery or AC
Power requirement	(100-240) VAC, 50/60Hz, 15VA; Rechargeable lithium battery, 3.7VDC	(100-240) VAC 50/60Hz 100VA; Rechargeable sealed lead-acid battery, 12V 2.3AH
Battery charging indicator	Available	Available
Low battery indicator	Available	Available
Battery charge time, typ.	Maximum 8 hours for charging	Maximum 13-15 hours for charging
Flammable anesthetics	N/A	N/A
Operating condition	Temperature: 5℃ ~ 40℃ Humidity: 30% ~ 80%, noncondensing Atmospheric pressure: 70.0kPa~106.0kPa	Temperature: 5℃ ~ 40℃ Humidity: 30% ~ 80%, noncondensing Atmospheric pressure: 70.0kPa~106.0kPa
Storage condition	Temperature: -20℃~60℃ Humidity: 10%~95%, noncondensing Atmosphere: 53kPa~106kPa	Temperature: -20℃~60℃ Humidity: 10%~95%, noncondensing Atmosphere: 53kPa~106kPa
EMC	The equipment meets the requirements of IEC 60601-1-2	The equipment meets the requirements of IEC 60601-1-2
Optional printer	N/A	Available

Build-in Function:

SpO_2 / Pulse Rate

Characteristics	Subject Device	Predicate Device
Name and model	All-in-One Health Monitor, PC-303	UP-7000 Patient Monitor
Manufacturer	Shenzhen Creative Industry Co., LTD.	Shenzhen Creative Industry Co., Ltd.
510(K) Number:	N/A	K123711
SpO_2 module	Identical	Creative SpO_2 module with the same principle as PC-60(K063641) Creative SpO_2 sensor only
Patient type	Identical	Adult, pediatric patients
SpO_2 measurement accuracy	Adult and Pediatric: ±3% (during 70%-100%) Undefined (during 0-70%)	Adult and Pediatric: ±3% (during 70%-100%) Undefined (during 0-70%)
Alarm range (%)	No Alarm	High Limit: 1%-100% Lower Limit. 0%-99%
Pulse rate measurement range	30 bpm-240 bpm	30 bpm-240 bpm
Pulse rate accuracy	±2bpm or ±2% (whichever is greater)	±2bpm or ±2% (whichever is greater)
Alarm range-Pulse rate (bpm)	No Alarm	High Limit: 1bpm-300bpm Lower Limit. 0bpm-299bpm

NIBP

Characteristics	Subject Device	Predicate Device
Name and model	All-in-One Health Monitor, PC-303	UP-7000 Patient Monitor
Manufacturer	Shenzhen Creative Industry Co., LTD.	Shenzhen Creative Industry Co., Ltd.
510(K) Number:	N/A	K123711
NIBP module	Creative B01-WK126 NIBP Module	SunTech Advantage 2.0 NIBP Module
Method	Oscillometric method	Oscillometric method
Patient type	Adult and Pediatric patients	Adult and Pediatric patients
Unit of measure	mmHg & kPa	mmHg & kPa
Pressure measurement range - Systolic	60 mmHg - 255mmHg	Adult: 40 mmHg - 260mmHg Pediatric: 40 mmHg - 160mmHg
Pressure measurement range - Diastolic	30 mmHg - 195mmHg	Adult: 20 mmHg - 200mmHg Pediatric: 20 mmHg - 120mmHg
BP accuracy	Mean deviation values: ±5 mmHg; Standard deviation < = 8 mmHg.	Mean deviation values: ±5 mmHg; Standard deviation < = 8 mmHg.
Cuff pressure range	0 to 300mmHg	0 to 300mmHg
Over pressure protector	Cuff pressure exceeds 300mmHg (Adult & Pediatric modes) at any time.	Internal operating software ensures that: -- o Maximum cuff inflation time is limited to 75 Seconds

				o **Duration of blood pressure reading is limited to 130 seconds (Adult mode), 90 seconds (Pediatric mode)** **Additional redundant safety circuitry oversees normal operation and will override to abort a reading if:** o **Cuff pressure exceeds 300 mmHg (Adult & Pediatric modes) at any time.** o **The cuff has been inflated for 180 seconds (Adult & Pediatric modes).**
Alarm setup	**Systolic**	**High Limit**	**No Alarm**	**Adult: 31 mmHg -280 mmHg** **Pediatric: 30 mmHg -200 mmHg**
		Lower Limit	**No Alarm**	**Adult: 29 mmHg -279 mmHg** **Pediatric: 29 mmHg -199 mmHg**
	Diastolic	**High Limit**	**No Alarm**	**Adult: 11 mmHg -232 mmHg** **Pediatric: 11 mmHg -150 mmHg**
		Lower Limit	**No Alarm**	**Adult: 10 mmHg -231 mmHg** **Pediatric: 10 mmHg -149 mmHg**
Alarm method			**No Alarm**	**Sound light alarm and record the alarm status for review**

TEMP

Characteristics	Subject Device	Predicate Device
Name and model	All-in-One Health Monitor, PC-303	UP-7000 Patient Monitor
Manufacturer	Shenzhen Creative Industry Co., Ltd.	Shenzhen Creative Industry Co., Ltd.
510(K) Number:	N/A	K123711
TEMP Module	Valeo VT-601E IR Ear thermometer cleared under K111463	TEMP module cleared under K982140
Fundamental scientific technology	Infrared technology	Thermo-resistor type
Patient type	Adult, Pediatric	Adult, Pediatric
Unit of measure	℃ or ℉	℃ or ℉
Measurement site	Ear	Body surface
Temperature measurement range	32.0℃ to 43.0℃ (90℉ to 109.5℉)	32.0℃ to 43.9℃ (90℉ to 109.9℉)
Temperature measurement accuracy	±0.2℃ (36.0℃ to 39.0℃), ±0.3℃ (the rest); ±0.4℉ (96.8℉ to 102.2℉), ±0.5℉ (the rest)	±0.1℃ (35.0℃ to 39.0℃) ±0.2℉ (95.0℉ to 102.2℉)

External Linked Functions (Optional):
The subject device is also capable to link and communicate with the legally marketed compatible Blood Glucose Meter and ECG monitor to take measurements.

Blood Glucose (K113077)

Name and model:	**G-777G BLOOD GLUCOSE MONITORING SYSTEM**
Manufacturer	**BIOLAND TECHNOLOGY LTD.**
510(K) Number:	**K113077**
Physical dimension/ weight	**81(L) X 62(W) X 19(H)/ 60g**
Test sites:	**Fingertip, forearm**
Power requirement	**CR2032 3V lithium coin battery x1**
Patient type	**Adult, pediatric patients**
Glucose Operating Range	**(1.1-33.3) mmol/L or (20-600) mg/dL**
Glucose Sample Types	**Whole Blood**
Glucose Sample volume	**0.7µl**
Glucose Hematocrit Compensation	**N/A**
Glucose Assay Time	**≤10s**
Calibration	**N/A**
Data Upload	**USB**
Compatible Test Strips	**N/A**
Operating condition	**Temperature: 10℃ - 40℃** **Humidity:20%-80%RH**
Connection Method with the subject device	**Connection Method:** **Using the optional link cable for the Blood Glucose Meter, connect the Blood Glucose Meter to the connector on the right side of the All-in-One Health Monitor marked "GLU" ("if"). When the device shows "**  **", this indicates that the blood glucose meter is linked successfully.** **Principle: The PC-303 All-in-One Health Monitor receives data from Blood Glucose Meter via the USB data interfaces for data communication, and the PC-303 looks over measurement result stored in Glucose Meter in real time.**

ECG (K073152)

Name and model:	**PC-80 Easy ECG Monitor**
Manufacturer	**Shenzhen Creative Industry Co., Ltd.**
510(K) Number:	**K073152**
Physical dimension/ weight	**115(L) X 58(W) X 18(H)/ 100g**
Type, Degree of protection against electric shock	**Internal power source, Type B**
Power requirement	**Two 1.5Vdc Alkaline battery (AAA)**
Patient type	**Adult, pediatric patients**
Number of electrodes employed	**3 embedded metal electrodes or using 3 adhesive ECG electrodes by connection to the lead wire**
Heart rate measuring range	**30bpm-240bpm**
Resolution	**1bpm**
Heart rate measuring precision	**±2bpm or ±2%, whichever is greater**
Sweep speed	**20mm/s±10%**
Signal bandwidth	**0.5Hz-40Hz**
Internal noise level	**≤30uVp-p**
CMRR	**≥60dB**
Display sensitivity	**4.8mm/mV±10%**
Operating condition	**Temperature: 5℃-40℃** **Humidity: ≤80%, noncondensing** **Atmospheric pressure: 86.0kPa-106.0kPa**
Storage condition	**Temperature: -20℃-55℃** **Humidity: ≤95%, noncondensing** **Atmosphere: 50kPa-106kPa**
EMC	**The equipment meets the requirements of IEC 60601-1-2**
Connection method with the subject device	**Connection Method:** **1. Connect the ECG accessory to the connector on the upper side of device marked "ECG".** **2. Choose one of the methods to take the ECG measurement.** **3. When the ECG accessory is connected to All-in-One Health Monitor successfully, press the "Start" button on the ECG accessory to activate the ECG measurement.** **4. When "ECG" appears on the display screen of the All-in-One Health Monitor, it means the ECG accessory has begun to take the ECG measurement.** **5. 30 Seconds later, the result will display on the screen of the terminal device, and the measurement will terminate.** **Principle: The PC-303 All-in-One Health Monitor receives data from Easy ECG Monitor via the USB data interfaces for data communication, and the PC-303 looks over measurement result stored in Easy ECG Monitor in real time.**

8. Safety and Performance Data:

Serial Number/Version	Standard and Description	Scope
IEC 60601-1: 1990+A1+A2+A13	Medical devices Part1: General requirements for safety and Amendment 1, Amendment 2 and Amendment 13	General requirements: Electrical Safety
IEC 60601-1-2: 2007	Medical electrical equipment- part 1-2: General requirements for basic safety and essential performance – Collateral standards: Electromagnetic compatibility –Requirements and tests	General requirements: EMC
IEC 60601-2-30: 2000	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers	General requirements: Software
IEC80601-2-30_NIBP	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers	General requirements: Usability
ISO80601-2-61_SpO2	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment	General requirements: Alarm system
IEC/TR60878: 2003	Graphical symbols for electrical equipment in medical practice	General requirements: Graphical symbols
ISO 10993-1:2009	Biological evaluation of medical devices--Part 1: Evaluation and testing	Biological evaluatio
ISO 10993-5:2009	Biological Evaluation of Medical Devices – Part 5 Tests for In Vitro Cytotoxicity.	General requirements: Biological Estimation
ISO 10993-10:2010	Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed-Type Hypersensitivity	General requirements: Biological Estimation
ISO 13485: 2003	Medical devices-Quality management systems-Requirements for regulatory purposes	Quality system

All of the test results noted in the table above were satisfactory.

Serial Number	Standard and Description	Scope
ECG K073152		
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	General requirements: Electrical Safety
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	General requirements: EMC
AAMI EC 38	Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems	Basic safety and essential performance of ambulatory electrocardiographic (ECG) systems
Temp-K111463		
ASTM E1965:1998(2009)	Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature	General Thermometer Performance
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	General requirements: Electrical Safety
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	General requirements: EMC

Serial Number	Standard and Description	Scope
SPO2 K063641		
IEC60601-1:1988 A1:1991,+ A2:1995	General requirements for Safety and Essential Performance	General requirements: Electrical Safety
IEC 60601-1-4	Medical Devices Part 1-4: General Requirements for Safety - Programmable Medical Electrical Equipment	General requirements Software
IEC 60601-1-1:2000	Medical electrical equipment -- Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems	General requirements: Electrical Safety
IEC60601-1-2:2007	Medical Electrical Equipment-Part 1-2:General Requirements for Safety - 2.Collateral Standard-Electromagnetic compatibility - Requirements and tests	General requirements: EMC

Serial Number	Standard and Description	Scope
IEC 61010-1: 2010	General requirements for Safety and Essential Performance	General requirements: Electrical Safety
IEC 61010-2-101	Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part 2-101: Particular Requirements for In Vitro Diagnostic (IVD) Medical Equipment	IVD General Safety Requirements
IEC 61326-1: 2012	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements	General requirements: EMC
IEC 61326-2-6	Electrical equipment for measurement, control and laboratory use. EMC requirements. Particular requirements. In vitro diagnostic (IVD) medical equipment	General requirements: EMC
ISO 15197	In vitro diagnostic test systems -- Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus	IVD Glucose performance and Safety
CLSI GP42-A6: 2008	Procedures and devices for the collection of diagnostic capillary blood specimens	General technique for capillary blood specimens
IEEE ISO 11073-10417	Health informatics -- Personal health device communication Part 10417: Device Specialization -- Glucose Meter	Communication between personal telehealth glucose meter devices and compute engines
ISO 10993-1: 2009	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process	Biological Evaluation

9. Testing Summary:

IEC 60601-1: 1990+A1+A2+A13: Testing was performed to validate the safety of this medical device. All the requirements of IEC 60601-1 were evaluated in this test report except the following clauses: 1) 12.2 & 15.1 Usability according to IEC/EN 60601-1-6 is not evaluated in this report. 2) 10.4 Lasers and light emitting diodes (LDEs) according to IEC/EN 60825-1 is not evaluated in this report. 3) 11.7 Biocompatibility of ME

EQUIPMENT and ME SYSTEMS according to ISO 10993 is not evaluated in this report. 4) 17 * Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS according to IEC 60601-1-2 is not evaluated in this report.

IEC 60601-1-2: 2007: Testing was performed to ascertain Electromagnetic Compatibility to other electrical devices. The testing performed was as follows:

Emissions tests: According to IEC 60601-1-2: 2014, ISO 80601-2-61:2011 Clause 202, ISO 80601-2-56:2009 Clause 202, IEC 80601-2-30: 2009+A1:2013 Clause 202, searching for the highest disturbance.

Immunity tests: According to IEC 60601-1-2: 2014, ISO 80601-2-61:2011 Clause 202, ISO 80601-2-56:2009 Clause 202, IEC 80601-2-30: 2009+A1:2013 Clause 202, searching for the highest disturbance.

Harmonics current: According to IEC 61000-3-2, searching for the highest disturbance.

Voltage fluctuation: According to IEC 61000-3-3, searching for the highest disturbance.

IEC 60601-2-30: 2000: Testing was performed to determine the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment. The equipment may be attended or unattended. The object of the testing was to establish particular adherence to requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment, with special attention being paid to the avoidance of hazards due to the inflation process. The PC-303 passed the safety requirements of this standard.

ISO80601-2-61_SpO2: The testing in performed to this standard was to establish particular basic safety and essential performance requirements for pulse oximeter equipment and its accessories. The PC-303 passed the safety requirements of this standard.

ISO 10993-5: Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity. The purpose of the test is to assess the potential cytotoxicity of test article Contact Lens Case in the In Vitro Cytotoxicity Test using L929 mouse fibroblast cells (From ATCC), which was sensitive to extractable cytotoxic articles. Under the conditions of this study, the test articles Contact Lens Case extract did not show potential toxicity to L-929 cells with polar and non-polar extracts.

ISO 10993-10: Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. The test was designed to evaluate the potential of a test article extract to cause ocular irritation. According to what observed, the response of ocular on testing side does not exceed that on the control side. Thus, it is identified as grade 0. All animals were not found abnormal clinical symptoms. except ocular reactions.
All animals were normal weight change. Under the conditions of this study, the test article extracts showed no significant evidence of causing ocular irritation.

ISO 10993-10: Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. The purpose of this test is to evaluate the potential of a test article extract to cause skin sensitization in the guinea pig. All animals were not found abnormal clinical symptoms except skin reactions. All animals were normal weight change. The positive rate of all test group animals was 0%. The positive rate of all negative control animals was 0%. Under the conditions of this study, the test article extract showed no significant evidence of causing skin sensitization in the guinea pig.

Performance Testing: Performance testing was performed to ensure that all of the device operated within specified parameters independently and with all other funcitons of the device operating. The testing also included wireless testing and the transfer of data via a USB. Each function operated within the design parameters, within the performance criteria established by the pertinent IEC standards. This established the equivalency to the predicate device.

10. Clinical:

Clinical testing was performed for the NIBP functions and are submitted as part of this submission.

The design of the submitted device specifications is substantially the same as the predicate, but adds a cleared NIBP module, made by SunTech.

All the labeling and characteristics of the submitted All-in-One Health Monitor, PC-303 are the same as the predicate device and most typical Patient Monitors currently on the market. The submitted device and predicate both are used for measuring patient SpO2, Pulse Rate, NIBP, TEMP and the optional linked functions of Blood Glucose and ECG.

11. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Shenzhen Creative Industry Co., Ltd. concludes that the All-in-One Health Monitor, PC-303 is substantially equivalent to predicate devices as described herein.

END