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: November 13, 2012

OCT 0 1 2013

1. Company and Correspondent making the submission:

Name – Shenzhen Creative Industry Co., Ltd.
Address – 2/F, Block 3, Nanyou Tian'an Industry Town, Hi-Tech Industrial Park(north), Shenzhen City, Guangdong Province
Telephone – +86-755-26434955
Fax – +86-755-26435433
Contact – Ms. Wang Jia
Email – charliemack@irc-us.com

2. Device :

Trade/proprietary name: Patient Monitor, UP-7000
Common Name : Patient Monitor
Classification Name :

Function	Product Code
ECG/RESP (including the Heart Rate)	MWI
SPO2 (functional oxygen saturation)	DQA
NIBP (Non-invasive blood pressure)	DXN
CO2 (end-tidal CO2 concentration) (including the Respiration Rate by the thorax impedance method (used with ECG lead)	CCK

3. Predicate Devices :

Description	Predicate Device #1	Predicate Device #2
Name and model	Vital Signs Monitor, PC-900A	PM-9000 Express Portable Patient Monitor
Manufacturer	Shenzhen Creative Industry Co., LTD.	Shenzhen Mindray Bio-medical Electronics Co., LTD.
510(K) Number	K093016	K053234

4. Classifications Names & Citations :

Function	Product Code	Citations
ECG/RESP (including the Heart Rate)	MWI	21CFR870.2300
SPO2 (functional oxygen saturation)	DQA	21CFR870.2300
NIBP (Non-invasive blood pressure)	DXN	21CFR870.2300
CO2 (end-tidal CO2 concentration) (including the Respiration Rate by the thorax impedance method (used with ECG lead)	CCK	21CFR868.1400

5. Description :

5.1 General

UP-7000 Patient Monitor is a modular designed patient monitor. It monitors the patient's Electrocardiograph (ECG), respiratory rate (RR) and bo dy temperature (TEMP) by measuring physical parameters with variety modules. It can also measure non-invasive blood pressure (NIBP, the pressures of systolic, diastolic and mean) by the oscillating method. It can detect the blood oxygen saturation (SpO_2) and pulse rate (PR) non-invasively by the photoelectric method. Finally, it can extend CO_2 monitor which measures the End-tidal Carbon dioxide, Inspired CO_2 and Respiratory Rate. The accessories and the sensors will transfer the physical parameters into electrical signal, which will be collected and amplified by the circuit in the device. After CPU analyzing and calculating, the parameters are displayed on the screen in a graphical representation and it can record and/or print if necessary. The alarm activates if the monitored parameters go over the specified limits, alerting the medical professional.

5.2 Features

This monitoring system may be used to monitor up to 10 of a patient's physical parameters: End-tidal Carbon Dioxide ($EtCO_2$), Inspired Carbon Dioxide ($InsCO_2$), ECG, heart rate, non-invasive blood pressure (NIBP), Respiratory Rate (RR), body temperature (TEMP), Pulse Oxygen Saturation (SpO_2), Pulse Rate and Perfusion Index (PI).

- It can measure SpO_2, Pulse Rate, and Perfusion Index; the plethysmogram can be displayed on LCD.
- It can measure End-tidal CO_2 ($EtCO_2$), Inspired CO_2 and Respiration Rate. The CO_2 waveform can be displayed on LCD.
- It can measure ECG, heart rate and Respiration Rate (RR). which enables simultaneous monitoring of several ECG waveforms and display on LCD.
- It can measure non-invasive blood pressure (NIBP) and body temperature (TEMP); the measure value can be displayed on LCD.
- Real-time monitoring of battery capacity, when the battery power is insufficient, low battery voltage alarm indication will display on LCD screen.
- The customer could use either mainstream or sidestream for the same monitor.

- Long-distance alarm function.
- Network function makes it to upload the stored data to a central station.
- 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 AC mains power supply.
- Built-in printer is optional.

6. Indication for use :

This Patient Monitor is a multi-functional instrument designed for monitoring the vital physiological signs of adult and pediatric patients. With the functions of real-time recording and displaying parameters, such as ECG, heart rate, non-invasive blood pressure, functional oxygen saturation, end-tidal CO2 concentration, respiration rate, body temperature, and so on, 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.

7. Comparison with predicate device :

The design of the Shenzhen Creative Industry Co., Ltd. UP-7000 monitor is very similar to the predicates and testing to the following standards: IEC 60601-1: 1990+A1+A2+A13 Medical devices Part1: General requirements for safety and Amendment 1, Amendment 2 and Amendment 13; IEC 60601-1-2: 2007 Medical electrical equipment-part 1-2; IEC 60601-1-4: 2000 Medical devices part 1-4; IEC 60601-1-6:2006 Medical electrical equipment-Part 1-6; IEC 60601-1-8: 2006 General requirements for basic safety and essential performance; IEC 60601-2-27 :2005 Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment; IEC 60601-2-49: 2001 Medical Electrical Equipment Part 2-49; ISO 7000 Graphical symbols for use on equipment—Registered symbols; ISO 21647: 2004(E) Medical electrical equipment-Particular requirements for the basic safety and essential performance of respiratory gas monitors; ISO 9919: 2005 Medical electrical equipment – Particular requirements for the basic safety and essential

performance of pulse oximeter equipment for medical use SpO2; ISO 15223: 2000 Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied; ISO/IEC GUIDE 37-1995 Instructions for use of products of consumer interest; ISO 10993-1:2009Biological evaluation of medical devices--Part 1: Evaluation and testing; ISO 10993-5:2009 Biological Evaluation of Medical Devices – Part 5 Tests for In Vitro Cytotoxicity; ISO 10993-10:2010 Biological Evaluation of Medical Devices – Part 10:Tests for Irritation and Delayed-Type Hypersensitivity; IEC 60068-2-6 Mechanical Vibration – Sine; IEC 60068-2-64: Mechanical Vibration – Random demonstrates that the Shenzhen Creative Industry Co., Ltd, Patient Monitor, model UP-7000 is substantially equivalent to the predicates, the Shenzhen Creative Vital Signs Monitor PC-900 and the Shenzhen Mindray PC-9000 Express.

8. Safety and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard EN/IEC 60601-1. Testing to specific ISO standards was used to validate the effectiveness and accuracy of the device. All test results were satisfactory.

9. 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 Patient Monitor, Model UP-7000 is safe and effective and substantially equivalent to predicate devices as described herein.

END,

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

October 1, 2013

Shenzhen Creative Industry Co., Ltd
c/o Mr. Charles Mack
Principal Engineer
12226 Washington Lane
Parker, AZ 85344

Re: K123711
Trade/Device Name: Patient Monitor/Model UP-7000
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II
Product Code: MWI, DQA, DXN, CCK
Dated: September 16, 2013
Received: September 20, 2013

Dear Mr. 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen D. Faris -S

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

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Patient Monitor, Model UP-7000

Indications for Use:

This Patient Monitor is a multi-functional instrument designed for monitoring the vital physiological signs of adult and pediatric patients. With the functions of real-time recording and displaying parameters, such as ECG, heart rate, non-invasive blood pressure, functional oxygen saturation, end-tidal CO2 concentration, respiration rate, body temperature, and so on, 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.

Prescription Use _X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.10.01 14:52:04 -04'00'