K093016

MAR 30 2010

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: September 6, 2009

1. Company and Correspondent making the submission:

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2. Device :

Trade/proprietary name: Vital Signs Monitor, Model PC-900A
Common Name : Oximeter
400 analyzer, gas, carbon-dioxide, gaseous-p
Classification Name : 21CFR870.2700, Oximeter, DQA
21CFR868.1400, 400 analyzer, gas, carbon-dioxide, gaseous-p, CCK

Predicate Devices:

Predicate Model	Manufacturer	K Number	Submitted Device
Capnostream 20	Oridion Capnography, Incorporated	K060065	Vital Signs Monitor, Model PC-900A
Vital Signs Monitor (Model M3B)	Edan Instruments, Incorporated	K083821	Vital Signs Monitor, Model PC-900A

3. Classifications Names & Citations :

21CFR 870.2700, DQA

21CFR868.1400, CCK

4. Description :

4.1 General

PC-900A vital signs monitor is a small Multi-parameter Patient Monitor, which can monitor the vital physiological parameters: Carbon Dioxide (CO_2), Pulse Oxygen Saturation (SpO_2), respiration and pulse 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. The specific sensors have been previously cleared by the FDA 510(k) process. (For specifics, please refer to the Description Section). After CPU analyzing and calculating, the parameters can display on the screen in a graphical way, record and/or print if necessary. The alarm will work if the parameters over the limits to take medical practitioner's attention.

5. Indication for use :

The Vital Signs Monitor is designed for monitoring the vital physiological signs of the patient. It is used for non-invasive continuous monitoring of oxygen saturation (SpO_2), pulse rate, CO_2 and respiration rate.

The Vital Signs Monitor is adaptable to adult and pediatric usage in a hospital environment. It is intended to be used only under regular supervision of clinical personnel.

6. Comparison with predicate device: - Please see next page for the comparison table.

Comparison with legally marketed predicate device

Element of comparison	Subject Device	Claimed SE Device 1	Claimed SE Device 2
Company	Shenzhen Creative Industry Co., Ltd.	Oridion Medical 1987 Ltd.	Edan Instruments, Inc.
FDA510(K) Number	N/A	K060065	K083821
Device Name	Vital Signs Monitor	Portable Bedside Capnograph/Pulse Oximeter	Vital Signs Monitor
Model Number	PC-900A	Capnostream™20	M3B
Power Supply	Battery or AC	Battery or AC	Battery or AC
Internal Power Supply	rechargeable sealed lead-acid battery, 12V 2.3AH	rechargeable Lithium-Ion battery, 14.8V 4.4AH	rechargeable Lithium-Ion battery, 14.8V 4.4AH
AC Power Supply	100~250V 50/60Hz 90VA	100~240V 50/60Hz 90VA	100~240V 50/60Hz 45VA
The type of protection against electric shock	Class I and internally powered per IEC 60601-1.	Class I and internally powered per IEC 60601-1.	Class I and internally powered per IEC 60601-1.
The degree of protection against electric shock	Type BF	Type BF	Type BF

Display	LED and LCD display	TFT Display	LCD display
Dimensions(mm)	360(L) × 320(D) × 410(H)	220 (L) x192 (D) x167 (H)	173.5(L) x 189(D) x 241(H)
Intended patient population	Adult, pediatric patients	Adult, pediatric and neonate patients	Adult, pediatric and neonate patients
Intended Use	The Vital Signs Monitor is designed for monitoring the vital physiological signs of the patient. It is use for non-invasive continuous monitoring of oxygen saturation (SpO_2), pulse rate, CO_2 and respiration rate. The Vital Signs Monitor is adaptable to adult and pediatric usage in a hospital environment. It is intended to be used only under regular supervision of clinical personnel.	The Capnostream2 0 is intended for CO2 and SPO2 indications. The Capnostream20 combined capnograph/pulse oximeter monitor is intended to provide professionally trained health care providers the continuous, non invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate, and for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO 2 and pulse rate). It is intended for use with neonatal, pediatric and adult patients in hospitals, hospital type facilities, intra hospital moves and home environments.	The Vital Signs Monitor is indicated for use for non-invasive continuous monitoring of oxygen saturation of the blood (SpO2) and C02. The Vital Signs Monitor is intended to be used only under regular supervision of clinical personnel. It is adaptable to adult, pediatric, and neonatal usage in a hospital environment and intra-hospital moves. The Vital Signs Monitor is equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both.

Nurse call function	Yes	Yes	Yes
SpO_2			
SpO_2 module	Creative SpO_2 module with the same principle as PC-60(K063641) Creative SpO_2 sensor only	Masimo SET pulse oximetry and Masimo SpO_2 Sensors	Nellcor Nell-1 OXI-Max SpO_2 module and Nellcor sensor
SpO_2 measure range	70%~99%	1%~100%	1%~100%
Accuracy of SpO_2	Adult and Pediatric: ±3% (during 70%~99%) Undefined (during 0~70%)	Adult and Pediatric: ±2% (during 70%~100%) Neonate: ±3% (during 70%~100%) Undefined (during 0~70%)	Adult and Pediatric: ±2% (during 70%-100%) Neonate: ±3% (during 70%-100%) Undefined (during 0~70%)
Alarm of SpO_2	High and lower alarms. The limits are adjustable.	High and lower alarms. The limits are adjustable.	The limit is adjustable.
Pulse rate display range	30 bpm~240 bpm	25 bpm ~240 bpm	20bpm~250bpm
Accuracy of pulse rate	±2bpm or ±2% (whichever is greater)	±3 bpm	±3bpm
Alarm of pulse rate	High and lower alarms. The limits are adjustable.	High and lower alarms. The limits are adjustable.	The limit is adjustable.
CO_2			

CO_2 module	Respironics LoFlo™ EtCO2 (Side-stream) Module(K053174) and CAPNOSTAT 5 EtCO2 (Main-stream) Module(K042601)	Microstream $EtCO_2$ Module	Respironics LoFlo™ $EtCO_2$ (Side-stream) Module and Repironics CAPNOSTAT 5 $EtCO_2$ (Main-stream) Module
CO_2 measurement method	Infrared absorption method	Microstream® non–dispersive infrared (NDIR) spectroscopy	Infrared absorption method
CO_2 measure mode	Sidestream or Mainstream	Sidestream	Sidestream or Mainstream
Measuring parameters	$EtCO_2$, $InsCO_2$ and Respiration Rate	EtCO2, FiCO2 and Respiration Rate	$EtCO_2$, $InsCO_2$ and Respiration Rate
CO_2 Response Time	Sidestream: <3seconds (includes transport time and rise time). Mainstream: <60ms (rise time)	2.95 s (typical)	<3seconds (includes transport time and rise time)
Units	mmHg, kPa or Vol%	mmHg, kPa or Vol%	mm Hg, kPa or %
CO_2 measure range	$EtCO_2$: 0~150mmHg $InsCO_2$: 3~50mmHg	CO_2, $EtCO_2$, $FiCO_2$ Range: 0~99 mmHg	$EtCO_2$: 0~99mmHg $InsCO_2$: 0~99mmHg
CO2 Accuracy	0~40 mmHg ±2mmHg 41~70 mmHg ±5% of reading 71~100 mmHg ±8% of reading 101~150mmHg±10% of reading	0~38 mmHg: ± 2 mmHg 39~99 mmHg: ± (5% of reading + 0.08% for every 1 mmHg above 38 mmHg)	0~40mmHg ±2mmHg 41~76mmHg ±8% of reading 77~99mmHg±10% of reading
Respiration Rate	2~150rpm (Sidestream) or	0~150 rpm	0~150bpm

measure range	0~150rpm (Mainstream)		
Respiration Rate accuracy	±2rpm	0~70 rpm: ±1 rpm 71~120 rpm: ±2 rpm 121~150 rpm: ±3 rpm	±2rpm
Flow Rate	50ml/min ±10 ml/min (Sidestream)	50 (42.5≤flow≤65) ml/min, flow measured by volume	50ml/min ±10 ml/min (Sidestream)
Suffocation Alarm Delay	10~60s	10~60s	10~40s
Alarm of $EtCO_2$	High and lower alarms. The limits are adjustable.	High and lower alarms. The limits are adjustable.	The limit is adjustable.
Alarm of RR	High and lower alarms. The limits are adjustable.	High and lower alarms. The limits are adjustable.	The limit is adjustable.

7. Safety and Performance Data :

   Please refer to the Declaration of Conformity for the comprehensive list of testing performed on the PC 900A Vital Signs Monitor. The PC 900A has undergone Third Party safety testing in accordance with IEC standards and completed performance testing in accordance with IEC standards. In that this device has software of Moderate concern; the appropriate level of Software evaluation was performed.

8. 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 Vital Signs Monitor, Model PC-900A, is safe and effective and substantially equivalent to predicate devices as described herein.

9. Shenzhen Creative Industry Co., Ltd. will update and include in a summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Shenzhen Creative Industry Company, Limited
C/O Mr. Charlie Mack
Principal Engineer
International Regulatory Consultants, LLC
77325 Joyce Way
Echo, Oregon 97826

MAR 30 2010

Re: K093016
Trade/Device Name: Vital Signs Monitor, Model PC-900A
Regulation Number: 21CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, CCK
Dated: March 18, 2010
Received: March 24, 2010

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Vital Signs Monitor, Model PC-900A

Indications for Use:

The Vital Signs Monitor is designed for monitoring the vital physiological signs of the patient. It is used for non-invasive continuous monitoring of oxygen saturation (SpO_2), pulse rate, CO_2 and respiration rate.

The Vital Signs Monitor is adaptable to adult and pediatric usage in a hospital environment. It is intended to be used only under regular supervision of clinical personnel.

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

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093016