K120502

510(k) Summary

DEC 07 2012

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

Date: October 15, 2012

1. Company:

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2. Device :

Trade/proprietary name	PC-60NW Fingertip Oximeter
Common Name	Oximeter
Classification Name	Oximeter

3. Predicate Devices :

Shenzhen Creative Industry Co., Ltd, PC-60 Fingertip Oximeter K063641
This submission is an Abbreviated 510(k) submission, based upon standards and the predicate is simply the original basis of the submitted device.

4. Classifications Names & Citations :

21CFR 870.2700 Oximeter, DQA, Class2

Description :

General

The pulse oxygen saturation is the percentage of HbO_2 in the total Hb in the blood, and the so-called O_2 concentration in the blood. It is an important bio-parameter for the respiration. Many of the respiration disease will cause hypoxemia, even damage the patient's life. As a result, monitoring the SpO_2 is indispensable in the clinical rescuing. The traditional monitoring method is to take the patient's blood sample and analyze the sample by the blood gas analyzer, measure out the O_2 pressure and calculate the SpO_2 finally. Traditionally SpO_2 measure is based on the clinical help of sapling human blood, and getting O_2 pressure by hemo-air analysis using hemo-air analyzer, then calculate the SpO_2. This method is inconvenient and discontinuous. For the purpose of measuring the SpO_2 more easily and accurately, our company developed the Fingertip Oximeter. The device can measure the body pulse simultaneously.

The PC-60NW Fingertip Oximeter is intended for measuring the pulse rate and functional oxygen saturation (SpO2) through patient's finger, and indicating the pulse intensity by a bar-graph display. This device is powered by 2 AAA batteries, it is small in size, convenient to use, and easy to carry. This device is applicable for spot-checking of SpO2 and pulse rate in home and clinic. The index finger is the recommended site. It is intended for spot-checking adult and pediatric patients on fingers between 1.0 -2.2 cm thick.

This oximeter has the function of wireless data transmission. The user can effectively transmit the data to computer through the wireless communication module.

5. Indication for use :

The PC-60NW Fingertip Oximeter is intended for measuring the pulse rate and functional oxygen saturation (SpO2) through patient's fing er, and indicating the pulse intensity by a bar-graph display.

This device is powered by 2 AAA batteries. This device is applicable for spot-checking of SpO2 and pulse rate in home and clinic for adult and pediatric patients. This device is recommended for use o n the index finger, for patients with fingers of 1.0 - 2.2 cm thick.

6. Comparison with predicate device :

Shenzhen Creative Industry Co., Ltd, PC-60 Fingertip Oximeter K063641

This submission is an Abbreviated 510(k) submission, based upon standards and the predicate is simply the original basis of the submitted device.

7. Safety and Performance Data :

Summary of Performance Testing

The Model PC-60 Fingertip Oximeter substantially has been tested in accordance with the system V & V plan and summary included with the submission using production equivalent units prior to release to market. A risk analysis identifying potential hazards and documenting mitigation of the hazards has been developed and applied as part of design control procedure. Shenzhen Creative Industry, LTD quality system confirms to 21CFR820, ISO 9001, ISO13485 and CMDCAS ISO 13485.
Testing performed to Electrical Safety IEC 60601-1-1:1988, EMC Requirements IEC 60601-1-2, Biocompatibility IEC 10993-1, SPO2 Basic Safety and performance ISO 9919:2005, Basic Electrical safety and performance for Pulse Oximeters, ISO 80610-2-61 and pertinent FDA guidance documents, complied with the specific requirements for safety and performance.

8. Differences between Predicate and Submitted PC60-NW:
The only difference between the submitted device and the predicate is in the display. The predicate uses a seven segment LCD to display the SPO2 and Pulse rate. Also the predicate displays the pulse amplitude with a 16 segment bar graph. The submitted device uses an OLED color dot matrix to display SPO2, Pulse Rate/perfusion index and plethysmogram and bar graph. The submitted device has two new features of automatic start-up two seconds after the finger is inserted and the new device has wireless PC connection capabilities.

9. Conclusions:

The performance data cited in the non- clinical testing performed is sufficient to demonstrate substantial equivalence to 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 Shenzhen Creative Industry Co., Ltd. concludes that the PC-60NW Fingertip Oximeter is safe and effective and complies with the acceptance criteria in the SP02 standards and FDA guidance documents 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 20993-002

Shenzhen Creative Industry Company, Limited
C/O IRC
Mr. Charles Mack
Principal Engineer
77325 Joyce Way
ECHO, OR 97826

DEC 0 7 2012

Re: K120502
Trade/Device Name: PC-60NW Fingertip Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: November 28, 2012
Received: December 04, 2012

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,

Kwame O. Ulmer

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

Enclosure

Indications for Use

510(k) Number (if known): K120502

Device Name: PC-60NW Fingertip Oximeter

Indications For Use:

The PC-60NW Fingertip Oximeter is intended for measuring the pulse rate and functional oxygen saturation (SpO2) through patient's finger, and indicating the pulse intensity by a bar-graph display.

This device is powered by 2 AAA batteries. This device is applicable for spot-checking of SpO2 and pulse rate in home and clinic for adult and pediatric patients. This device is recommended for use on the index finger, for patients with fingers of 1.0 - 2.2 cm thick.

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)

Lester W. Schultheis Jr
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120502