K131111/S002

Attachment 3

510(k) Summary

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

1.0 submitter's information

Name: Andon Health Co., Ltd.
Address: No 3, Jinping Street Ya An Road, Nankai District, Tianjin, P.R. China
Phone number: 86-22-6052 6161
Fax number: 86-22-6052 6162
Contact: Liu Yi
Date of Application: 04/08/2013

SEP 1 1 2013

2.0 Device name

Device name: iHealth PO3M Fingertip Pulse Oximeter

3.0 Classification

Production code: DQA - Oximeter
Regulation number: 870.2700
Classification: II
Panel: Cardiovascular

4.0 Predicate device information

Manufacturer: Andon Health Co., Ltd.
Device: APO-8284 Fingertip Pulse Oximeter
510(k) number: K121697

5.0 Intended use

The PO3M Fingertip Pulse Oximeter is a non-invasive device intended for spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. The portable fingertip device is indicated for adult patients in home and hospital environments (including clinical use in internist/surgery, anesthesia, intensive care, etc).

6.0 Device description

Our device PO3M Fingertip Pulse Oximeter is a fingertip device, which can measure the arterial SpO2 and pulse rate value and can display the results to the user.

It is a noninvasive measurement instrument with a pair of small light-emitting diodes (LEDs) facing a photodiode through a fingertip. One LED is red, with wavelength of 660 nm, and the other is infrared, 880 nm. The MCU calculates the ratio of these two wavelengths and get the results of the SPO2. At the same time, by examining only the varying part of the absorption spectrum, a monitor can ignore other tissues or nail, and discern only the absorption caused by arterial blood to detect the pulse rate.

The power source is Lithium-ion battery.

More over, the PO3M can transmit the measurement data to the iPhone, iPod Touch or iPad by wireless transmission.

The device is for prescription. It is neither for life-supporting nor for implanting. It does not contain any drug or biological product and it does not need to be sterile.

The intended use and the indication for use of PO3M Fingertip Pulse Oximeter, as described in the labeling are the same as their predicated device APO-8284 Fingertip Pulse Oximeter (K121697)

7.0 Summary comparing technological characteristics with predicate device

Technological Characteristics	Comparison result
Design principle	Identical
Appearance	Similar
Patients contact Materials	Identical
Performance	Identical
Biocompatibility	Identical
Mechanical safety	Identical
Energy source	Identical
Standards met	Identical
Electrical safety	Identical
EMC	Identical
Function	Similar

8.0 Non-clinical Testing Summary

The following testing was performed on the iHealth PO3M Fingertip Pulse Oximeter in accordance with the requirements of the design control regulations and established quality assurance procedures.

(1) Biocompatibility of materials

Materials used on the new device PO3M that contact with the patient is exactly the same as the predicate device APO-8284(K121697). Because the material only contact with the user's intact skin within 24 hours, so according to ISO 10993-1, the cytotoxicity, sensitization, and irritaion testing have been performed on the final finished device material according to the following standards, and found to meet the applicable requirements:

ISO 10993-1: 2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
ISO 10993-5: 2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
ISO 10993-10: 2002/Amd. 1:2006(E), Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity AMENDMENT 1

(2) Electromagnetic Compatibility

The device was tested according to IEC 60601-1-2, and also conform to the requirements set in ISO 80601-2-61, Particular Requirements for Basic Safety and Essential Performance of Pulse Oximeter Equipment. The test result show that, the device meet all the applicable requirements.

(3) Electrical Safety Testing

The device was tested according to IEC 60601-1: 2005+ CORR.1(2006)+CORR.2(2007), and IEC 60601-1-11:2010, and also conform to the requirements set in ISO 80601-2-61, Particular Requirements for Basic Safety and Essential Performance of Pulse Oximeter Equipment. The test result show that, the device meet all the applicable requirements.

(4) Performance Testing

The device was tested according to ISO 80601-2-61: 2011-Particular Requirements for Basic Safety and Essential Performance of Pulse Oximeter Equipment. And found the device meet all the applicable requirements.

9.0 Comparison to the predicate device and the conclusion

The applicant device Fingertip Pulse Oximeter is substantially equivalent to PO3M Fingertip Pulse Oximeter whose 510(k) number is K121697.

Similarities and differences comparision		
Characteristics	**Subject device PO3M**	**Predicate device APO-8284 (K121697)**
Intended use	The PO3M Wireless Pulse Oximeter is a non-invasive device intended for spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. The portable fingertip device is indicated for adult patients in home and hospital environments (including	The APO-8284 Fingertip Pulse Oximeter is a non-invasive device intended for spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. The portable fingertip device is indicated for adult patients in home and hospital environments (including

	clinical use in internist/surgery, anesthesia, intensive care, etc). The PO3M Wireless Pulse oximeter is not intended for continuous monitoring.	clinical use in internist/surgery, anesthesia, intensive care, etc). The APO-8284 Fingertip Pulse oximeter is not intended for continuous monitoring.
Design priciple	See section 6	See section 6
Presentation or OTC	Presentation	Presentation
Contact material	Silica gel	Silica gel
SpO2 measuring range	70%-99%	70%--99%
SpO2 Accuracy	±2%	±2%
Pulse Rate Measuring Range	30-250bpm	30-250bpm
Pulse Rate Accuracy	± 2 bpm during the pulse rate range of 30-99 bpm and 2% during the pulse rate range of 100-250 bpm	± 2 bpm during the pulse rate range of 30-99 bpm and 2% during the pulse rate range of 100-250 bpm
Operation Temperature	5℃-40℃	5℃-40℃
Power Source	330mAh Lithium-ion battery	2*AAA or rechargeable batteries
Operation Humidity	<80%	<80%
Other function	low battery voltage alarm: automatically power off	low battery voltage alarm: automatically power off

As a result, PO3M is very similar with its predicate device in the intended use, the design principle, the material, the performance and the applicable standards. Only their appearance, the power source and the wireless data transmission function are different. However, the test in this submission provides demonstration that these small differences do not raise any new questions of safety and effectiveness to the new devices.

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 11, 2013

Andon Health Co., Ltd.
Liu Yi, President
#3, Jin Ping St. Ya An Rd.
Nankai District
Tianjin, China 300190

Re: K131111
Trade/Device Name: iHealth PO3M Fingertip Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: August 8, 2013
Received: August 12, 2013

Dear Mr. Yi:

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.

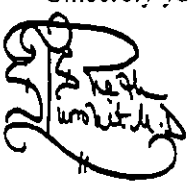
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



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FOR

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number : K131111

Device name: iHealth PO3M Fingertip Pulse Oximeter

Indications for use:

The PO3M Wireless Pulse Oximeter is a non-invasive device intended for spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. The portable fingertip device is indicated for adult patients in home and hospital environments (including clinical use in internist/surgery, anesthesia, intensive care, etc).

Prescription use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-COUNTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lester W. Schultheis Jr
2013.09.10 15:38:01 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Respiratory, Infection Control and
Dental Devices
510(k) Number: K131111