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

June 3, 2015

Shenzhen Creative Industry Co., Ltd.
c/o Mr. Charles Mack
IRC
12226 Washington Lane
Parker, Arizona 85344

Re: K150093
Trade/Device Name: Pulse Oximeter PC-66A; PC-66B; PC-66C; PC-60B1; PC-60B5; PC-60D; PC-60D2; PC-60E; PC-60N; POD-1; POD-2; POD-3; POD-1W; PC-60NW-1; PC-68A; PC-68B; and PC-68C.
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: April 12, 2015
Received: May 4, 2015

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,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental 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)*
K150093

Device Name
Pulse Oximeter
PC-66A; PC-66B; PC-66C;PC-60B1; PC-60B5; PC-60D; PC-60D2; PC-60E; PC-60N;POD-1; POD-2; POD-3;POD-1W;PC-60NW-1; PC-68A; PC-68B; PC-68C.

Indications for Use *(Describe)*
The Pulse Oximeters are intended for measuring the pulse rate and functional oxygen saturation (SpO2) through patient's finger, indicating the pulse intensity by a bar-graph display.

These devices are used for spot-checking a patient's SpO2 and pulse rate in a home or clinical environment. They are intended to be used by adult and pediatric patients. These devices are recommended for use on the index finger, for patients with fingers of 1.0 - 2.2 cm thick.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

Date: April 10, 2015

1. Company:

Name – Shenzhen Creative Industry Co., Ltd.

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Telephone – +86-755-26431671

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Contact – Mrs. Jia Wang

Email charliemack@irc-us.com

Correspondent:

Name- IRC

Address- 12226 Washington Lane, Parker, Arizona 85344

Telephone- 931-625-4938

Contact- Charlie Mack

Email- charliemack@irc-us.com

2. Device :

Trade/proprietary name	Pulse Oximeter: PC-66A; PC-66B; PC-66C;PC-60B1; PC-60B5; PC- 60D; PC-60D2; PC-60E; PC-60N; POD-1; POD-2; POD-3; PC-68A; PC-68B; PC-68C; POD-1W; POD- 60NW-1
Common Name	Oximeter
Classification Name	Oximeter

3. Predicate Devices :

Shenzhen Creative Industry Co., Ltd, PC-60 Fingertip Oximeter K063641and PC 60 NW Fingertip Oximeter K120502.

This submission is a Special 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

5. Description :

5.1 General

A blood-oxygen saturation reading indicates the percentage of hemoglobin molecules in the arterial blood which are saturated with oxygen. The reading may be referred to as SaO2. Readings vary from 0 to 100%. Normal readings in a healthy adult, however, range from 94% to 100%. The term SpO_2 means the SaO2 measurement determined by pulse oximetry. In its most common (transmissive) application mode, a sensor device is placed on a thin part of the patient's body. The device passes two wavelengths of light through the body part to a photodetector. It measures the changing absorbance at each of the wavelengths, allowing it to determine the absorbances due to the pulsing arterial blood alone, excluding venous blood, skin, bone, muscle and fat. For the purpose of measuring the $SpO_{2\,more}$ easily and accurately, our company developed the Fingertip Oximeter. The device can measure $SpO_{2\,and}$ body pulse simultaneously.

The PC-66A; PC-66B; PC-66C;PC-60B1; PC-60B5; PC-60D; PC-60D2; PC-60E; PC-60N; POD-1; POD-2; POD-3; PC-68A; PC-68B; PC-68C; POD-1W; POD-60NW-1 Fingertip Oximeter is intended for measuring the pulse rate and functional oxygen saturation (SpO2) through patient’s finger, 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 a home and clinical environment. 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 a wireless data transmission function. The user can transmit the SPO_2 and pulse rate data to a computer through the wireless communication module.

6. Indication for use :

The Pulse Oximeters are intended for measuring the pulse rate and functional oxygen saturation (SpO2) through patient's finger, indicating the pulse intensity by a bar-graph display.

These devices are used for spot-checking a patient's SpO2 and pulse rate in a home or clinical environment. They are intended to be used by adult and pediatric patients. These devices are recommended for use on the index finger, for patients with fingers of 1.0 - 2.2 cm thick.

7. Comparison with predicate device :

Please refer to the table on the following page for a comparison between the predicates and the submitted devices.

The submitted devices are compared to the Shenzhen Creative Industry Co., Ltd, PC-60 Fingertip Oximeter K063641 and PC 60 NW Fingertip Oximeter, K120502.

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

Submitted Device	Predicate	Differences
PC-66A	PC-60- K063641	The specific differences between the submitted PC 66A and predicate is the size of the LCD screen, the physical dimensions, and a variation in the body style. None of the electronics or sensors have been altered with this new device. The changes are made for marketing purposes and do not affect the performance, as none of the components which affect operation have been altered. The altered case still maintains the same thickness for to protect the circuitry. The body color of the submitted device is a different color and the new material has undergone biocompatibility testing to validate for patient use.
PC-66B	PC-60- K063641	The specific differences between the submitted PC 66B and predicate is the size of the LCD screen, changes from a LCD to an OLED (organic LED display), body color and a variation in the body style. The only variation in the body style is the submitted device has a dimpled surface at one end, while the predicate has two ripples. None of the electronics or sensors have been altered with this new device. The changes are made for marketing purposes and do not affect the performance, as none of the components which affect operation have been altered. The altered case still maintains the same thickness to protect the circuitry. The material for the outer shell has undergone biocompatibility testing.
PC-66C	PC-60- K063641	The specific differences between the submitted PC 66B and predicate is the size of the LCD screen, changes from a LCD to an OLED (organic LED display), body color and a variation in the body style. The only variation in the body style is the submitted device has a dimpled surface at one end, while the predicate has two ripples. None of the electronics or sensors have been altered with this new device. The changes are made for marketing purposes and do not affect the performance, as none of the components which affect operation have been altered. The altered case still maintains the same thickness to protect the circuitry. The material for the outer shell has undergone biocompatibility testing.

Submitted Device	Predicate	Differences
PC-60B1	PC-60- K063641	The specific differences between the submitted PC 66B and predicate is the size of the LCD screen, changes from a LCD to an OLED (organic LED display), body color and a variation in the body style. The only variation in the body style is the submitted device has a smooth surface at one end, while the predicate has two ripples. The LCD screen on the submitted device has been shifted to display from the side rather than the top down version of the predicate. The readings are still easy to see. None of the electronics or sensors have been altered with this new device. The changes are made for marketing purposes and do not affect the performance, as none of the components which affect operation have been altered. The altered case still maintains the same thickness to protect the circuitry. The material for the outer shell has undergone biocompatibility testing.
PC-60B5	PC-60- K063641	The specific differences between the submitted PC 60B5 and predicate is the size of the LCD screen, changes from a LCD to an OLED (organic LED display), body color and a variation in the body style. The only variation in the body style is the submitted device has a dimpled surface at one end, while the predicate has two ripples. None of the electronics or sensors have been altered with this new device. The changes are made for marketing purposes and do not affect the performance, as none of the components which affect operation have been altered. The altered case still maintains the same thickness to protect the circuitry. The material for the outer shell has undergone biocompatibility testing.
PC-60D	PC-60- K063641	The specific differences between the submitted PC 60D and predicate is the size of the LCD screen, changes from a LCD to an OLED (organic LED color display), body color and a variation in the body style. The only variation in the body style is the submitted device has a dimpled surface at one end, while the predicate has two ripples. None of the electronics or sensors have been altered with this new device. The changes are made for marketing purposes and do not affect the performance, as none of the components which affect operation have been altered. The altered case still maintains the same thickness to protect the circuitry. The material for the outer shell has undergone biocompatibility testing.

Submitted Device	Predicate	Differences
PC-60D2	PC-60- K063641	The specific differences between the submitted PC 60D2 and predicate is the size of the LCD screen, color and a variation in the body style. The only variation in the body style is the submitted device is 3 mm longer and wider and 3 mm thinner. None of the electronics or sensors have been altered with this new device. The changes are made for marketing purposes and do not affect the performance, as none of the components which affect operation have been altered. The altered case still maintains the same thickness to protect the circuitry. The material for the outer shell has undergone biocompatibility testing.
PC-60E	PC-60- K063641	The specific differences between the submitted PC 60E and predicate is the size of the LCD screen, changes from a LCD to an OLED (organic LED color display), body color and a variation in the body style. The only variation in the body style is the submitted device is 3 mm larger in all length and thickness and 3 mm thinner. None of the electronics or sensors have been altered with this new device. The changes are made for marketing purposes and do not affect the performance, as none of the components which affect operation have been altered. The altered case still maintains the same thickness to protect the circuitry. The material for the outer shell has undergone biocompatibility testing.
PC-60N	PC-60- K063641	The specific differences between the submitted PC 60N and predicate is the size of the LCD screen, changes from a LCD to an OLED (organic LED color display), body color and a variation in the body style. The only variation in the body style is the submitted device is 3 mm larger in all length and thickness and 3 mm thinner. None of the electronics or sensors have been altered with this new device. The changes are made for marketing purposes and do not affect the performance, as none of the components which affect operation have been altered. The altered case still maintains the same thickness to protect the circuitry. The material for the outer shell has undergone biocompatibility testing.

Submitted Device	Predicate	Differences
POD-1	PC-60- K063641	The specific differences between the submitted POD-1 and predicate is the size of the LCD screen, color and a variation in the body style. The only variation in the body style is the submitted device is 3 mm larger in all length and thickness and 3 mm thinner. None of the electronics or sensors have been altered with this new device. The changes are made for marketing purposes and do not affect the performance, as none of the components which affect operation have been altered. The altered case still maintains the same thickness to protect the circuitry. The material for the outer shell has undergone biocompatibility testing.
POD-2	PC-60- K063641	The specific differences between the submitted POD-2 and predicate is the size of the LCD screen, color and a variation in the body style. The only variation in the body style is the submitted device is 3 mm larger in all length and thickness and 3 mm thinner. None of the electronics or sensors have been altered with this new device. The changes are made for marketing purposes and do not affect the performance, as none of the components which affect operation have been altered. The altered case still maintains the same thickness to protect the circuitry. The material for the outer shell has undergone biocompatibility testing.
POD-3	PC-60- K063641	The specific differences between the submitted POD-3 and predicate is the size of the LCD screen, color and a variation in the body style. The only variation in the body style is the submitted device is 3 mm larger in all length and thickness and 3 mm thinner. None of the electronics or sensors have been altered with this new device. The changes are made for marketing purposes and do not affect the performance, as none of the components which affect operation have been altered. The altered case still maintains the same thickness to protect the circuitry. The material for the outer shell has undergone biocompatibility testing.

Submitted Device	Predicate	Differences
PC-68A	PC-60NW K120502	The specific differences between the submitted PC-68A and predicate is the changes from a LCD to an OLED (organic LED color display), body color and a variation in the body style. The only variation in the body style is the submitted device is 3 mm larger in all length and thickness and 3 mm thinner. None of the electronics or sensors have been altered with this new device. The changes are made for marketing purposes and do not affect the performance, as none of the components which affect operation have been altered. The altered case still maintains the same thickness to protect the circuitry. The material for the outer shell has undergone biocompatibility testing.
PC-68B	PC-60NW K120502	The specific differences between the submitted PC-68B and predicate is the size of the LCD screen, changes from a LCD to an OLED (organic LED display), body color and a variation in the body style. The only variation in the body style is the submitted device is 3 mm larger in all length and thickness and 3 mm thinner. None of the electronics or sensors have been altered with this new device. The changes are made for marketing purposes and do not affect the performance, as none of the components which affect operation have been altered. The altered case still maintains the same thickness to protect the circuitry. The material for the outer shell has undergone biocompatibility testing.
PC-68C	PC-60NW K120502	The specific differences between the submitted PC-68B and predicate is the size of the LCD screen, changes from a LCD to an OLED (organic LED color display), body color and a variation in the body style. The variation in the body style is the submitted device is 3 mm larger in all length and thickness and 3 mm thinner. The submitted device also has a depression at one end of the upper body. None of the electronics or sensors have been altered with this new device. The changes are made for marketing purposes and do not affect the performance, as none of the components which affect operation have been altered. The altered case still maintains the same thickness to protect the circuitry. The material for the outer shell has undergone biocompatibility testing.

Submitted Device	Predicate	Differences
POD-1W	PC-60NW K120502	The specific difference between the submitted POD-1W and predicate is the color. None of the electronics or sensors have been altered with this new device. The changes are made for marketing purposes and do not affect the performance, as none of the components which affect operation have been altered. The altered case still maintains the same thickness to protect the circuitry. The material for the outer shell has undergone biocompatibility testing.
POD-60NW-1	PC-60NW K120502	The only attribute that is different in these is that the changes from a LCD to an OLED (organic LED display). One device reads top down and the other reads from the bottom up.

8. Performance Data :

No.	Category	Directives/Standards	Title & Comments
1	General	93/42/EEC	Medical Device Directive
		21CFR820	Code of Federal Regulations
		IEC60601-1:2005	General requirements for Safety and Essential Performance
		ISO14971 Second edition 2007-03-01	Medical devices-Application of risk management to medical devices
2	EMC	IEC60601-1-2:2007	Medical Electrical Equipment-Part 1-2:General Requirements for Safety - 2.Collateral Standard-Electromagnetic compatibility - Requirements and tests
3	Biocompatibility	ISO 10993-1:2009	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
		ISO10993-5: 2009	Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
		ISO10993-10: 2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
4	Labeling	FDA Guidance	Labelling Regulatory Requirements for Medical Devices
5	SpO2	ISO 80601-2-61 First edition 2011-04-01	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
		IEEE/ISO 11073-10404 First edition 2010-05-01	Health informatics - Personal health device communication - Part 10404: Device specialization - Pulse oximeter
		FDA Guidance	Pulse Oximeters - Premarket Notification Submissions [510(k)s] issued on Mar.4,2013
		FDA Guidance	General Guidance Document: Non-Invasive Pulse Oximeter

9. Design Control Activities

Shenzhen Creative Industry Co., Ltd.'s manufacturing facility is in compliance with the design control procedure requirements as specified in 21 CFR 820.30 of FDA GMP CFR820 Quality System Regulation and the records are available for review.

All the design changes have been evaluated and the related verification and validation activities were performed by qualified designated individuals and the results demonstrated that the predetermined acceptance criteria for the submitted devices was met.

The difference between the new devices and predicate devices are display screen, physical dimension, appearance and color.

The new devices comply with applicable electric safety and EMC standards. These standards are the same as used to test the predict devices.

The design changes between the new models and predicate device did not alter the light emitter or the receive sensor. The electronics in all of the submitted devices is exactly the same as our predicate devices. Critical dimensions, alignment and case thickness did not change. The case maintains the same integrity to protect the electronics and the LCD is the same segment digital display with the same visibility as the predicate. Testing was performed for Electrical Safety and EMC. The new devices comply with the same standards as the predict devices, which are noted below:

- IEC 60601-1

- IEC 60601-1-2

- ISO 80601-2-61:2011 Clauses 201.17 and 202

The table below is a synopsis of the testing performed.

Verification Test	Standards/Method	Tests Performed
Electric Safety	IEC 60601-1: 2005	7.1.2 Legibility of marking 7.1.3 Durability of marking test 8.7 Leakage current 8.8.3 Dielectric strength test 8.8.4.1 Ball pressure test of thermoplastic parts 11.1.1 Excessive temperatures test 13.2 Single fault condition test 15.3 Mechanical strength tests

<table>
<tr><th>Verification Test</th><th>Standards/Method</th><th>Tests Performed</th></tr>
<tr><td rowspan="3">EMC</td><td>IEC 60601-1-2: 2014

CISPR 11: 2010

ISO 80601-2-61:2011 Clauses 201.17 and 202</td><td>Radiated emission (Class B):
<table><tr><th>Frequency (MHz)</th><th>Distance (Meters)</th><th>Limits (dBuV/m)</th></tr><tr><td>30-230</td><td>3</td><td>40</td></tr><tr><td>230-1000</td><td>3</td><td>47</td></tr></table></td></tr>
<tr><td>IEC 60601-1-2: 2014

IEC 61000-4-2: 2008

ISO 80601-2-61: 2011 Clauses 201.17 and 202</td><td>Electrostatic discharge: Contact discharge: 6kV, 10 times

Air discharge: 8kV, 25 times</td></tr>
<tr><td>IEC 60601-1-2: 2014

IEC 61000-4-3: 2010

ISO 80601-2-61: 2011 Clauses 201.17 and 202</td><td>RF field strength susceptibility:

Frequency range: 80MHz to 2.7 GHz

Field strength: 10V/m</td></tr>
<tr><td></td><td>IEC 60601-1-2: 2014

IEC 61000-4-8: 2010

ISO 80601-2-61: 2011 Clauses 201.17 and 202</td><td>Power frequency magnetic field susceptibility test:
Test frequency: 50Hz, 60Hz
Continuous field: 30 A/m
Test duration: 5min
Antenna factor: 0.917A/m</td></tr>
</table>

The new devices comply with the biocompatibility requirement defined in ISO10993-1. These are the tests performed on the predicate devices.

The table below is a synopsis of the biocompatibility testing performed on the submitted devices. This is the same battery of biocompatibility tests performed on the predicate devices.

Verification Test	Standards/Method	Tests Performed
In Vitro Cytotoxicity	ISO10993-5: 2009 MTT Method	8.5 Determination of cytotoxicity
Skin Sensitization	ISO10993-10: 2010 GPMT Method: Guinea Pig Maximization Test (0.9% Sodium Chloride Extract)	7.5.6 Evaluation of results
Skin Irritation	ISO10993-10: 2010 6.3 Animal skin irritation test	6.3.6 Evaluation of results

Cleaning and disinfection instructions:

The cleaning and disinfection instruction is same as predicate device. With no change, no verification need was deemed necessary.

Clinical validation of SpO_2 :

For all of the submitted devices, the only change is enclosure color, but no change was done for the color of the cushion rubber (material contacting the patient's finger during measuring).

In that the measuring device in the electro-circuit module, cushion rubber, emitter and receiver are the same as predicate devices, we concluded that this will not affect the device performance. No new clinical validation needed.

Bench Test of SpO2 and Pulse Rate

All new devices are exactly same as predicate devices in measuring electro-circuit module (cushion rubber, emitter and receiver). Generally, new tests are not needed.
Taking a conservative approach to performance, we conducted additional verification to show it complies with the requirement, refer to below summary:

Verification Test	Standards/Method	Tests Performed
Safety and Performance	ISO 80601-2-61: 2011	201.11 Protection against excessive temperatures
		201.11.6.5.101 Ingress of water IPX1, test by 14.2.1 of IEC60529: 2001
		201.15.3.5.101.1a) Shock test (IEC 60068-2-27: 2008 Test Type1)
		201.15.3.5.101.1b) Vibration test (IEC 60068-2-64: 2008 Broad-band random vibration test)
Performance Parameter Test	Sp02 simulator method (simulator model: Index 2 series)	SpO2 measuring range: 0%-99% SpO2 measuring accuracy: 70%""100% +3%; ""69% no defined 0%
		PR measuring range: 30bpm-240bpm PR measuring accuracy: ±2bpm or ±2% (whichever is greater)

10. 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 Fingertip Oximeter, models PC-66A; PC-66B; PC-66C;PC-60B1; PC-60B5; PC-60D; PC-60D2; PC-60E; PC-60N; POD-1; POD-2; POD-3; PC-68A; PC-68B; PC-68C; POD-1W; POD-60NW-1 is substantially equivalent to the predicate devices and complies with the acceptance criteria in the SP02 standards and FDA guidance documents as described herein.

END