Shenzhen IMDK Medical Technology Co., Ltd.
% Kevin Wang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
22A, Haijing Square
No. 18, Taizi Road
Nanshan District, Shenzhen, 518067 Cn

Re: K173123
Trade/Device Name: Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: July 12, 2018
Received: July 12, 2018

Dear Kevin Wang:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd D. Courtney -S

for Tina Kiang, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173123

Device Name
Pulse Oximeter

Indications for Use *(Describe)*

Fingertip Pulse Oximeter C101H1 is a non-invasive device intended for spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). This portable device is indicated for use in adult patients in hospitals.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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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

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2017/09/20

1. Submission sponsor

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2. Submission correspondent

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3. Subject Device Information

Trade/Device Name	Pulse Oximeter
Model	C101H1
Common Name	Pulse Oximeter
Regulatory Class	Class II
Classification	21CFR 870.2700 / Oximeter / DQA
Submission type	Traditional 510(K)

4. Predicate Device

AMEMO Inc. Fingertip Pulse Oximeter A310/ K153021.

The subject device has same intended use, same target patient population, and same performance effectiveness as the predicate device and there are no different questions of effectiveness and safety. So, the conclusion is that the subject device is substantial equivalent to the predicate.

5. Device Description

SpO2 is based on the absorption of pulse blood oxygen to red and infrared light by means of finger sensor and SpO2 measuring unit. The light-electronic transducer in finger sensor converts the pulse red and infrared light modulated by pulse blood oxygen into electrical signal, the signal is processed by hardware and software of the unit. The PLETH curve and numeral value of SpO2 will be obtained.

The pulse oximeter, C101H1, is designed for spot checking of the pulse oxygen saturation and pulse rate

for adults in a clinic environment. This medical device can be reused. Not for continuously monitoring.
The device is not for life-supporting or life-sustaining, not for implant.
The device is not provided sterile and is NOT a reprocessed single-use device.
The device is a spot-check pulse oximeter and does not include alarms.
The device does not support the measurement in the condition of low perfusion.
The device is not intended for life-supporting or life-sustaining.
The device is reusable and does not need sterilization.

6. Intended use & Indication for use

Fingertip Pulse Oximeter C101H1 is a non-invasive device intended for spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). This portable device is indicated for use in adult patients in hospitals.

7. Predicate Device Comparison

The subject devices share the same characteristics in all items with the predicate device, concluding from using the same technology and principle. All the technological differences existed between the subject and predicate devices are only some performance parameters improvement, detailed substantial equivalence discussion is included in the following tables.

Comparison Items	**Proposed device: C101H1**	**Predicate device: A310 (K153021)**
Intended use/ Indications for use	Fingertip Pulse Oximeter C101H1 is a non-invasive device intended for spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). This portable device is indicated for use in adult patients in hospitals.	Fingertip Pulse Oximeter A310 is a non-invasive device intended for spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). This portable device is indicated for use in adult patients in hospitals
Principle	The device displays numerical values for functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate by measuring the absorption of red and infrared (IR) light passing through perfused tissue. Changes in the absorption caused by the pulsation of blood in the vascular	The device displays numerical values for functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate by measuring the absorption of red and infrared (IR) light passing through perfused tissue. Changes in the absorption caused by the pulsation of blood in the vascular

Comparison Items		Proposed device: C101H1	Predicate device: A310 (K153021)
		bed are used to determine oxygen saturation and pulse rate.	bed are used to determine oxygen saturation and pulse rate.
Specification	**LED wavelength**	Red= 660 nm; Infrared=904nm	Red= 660 nm; Infrared=905nm
	Power source	2 AAA alkaline batteries.	2 AAA alkaline batteries.
	Display data	SpO2%; PR	SpO2%; PR
	SpO2 Measuring Range	0%-100%	0%-100%
	SpO2 Resolution	1%	1%
	SpO2 Accuracy	70~100%, ±3%;	70~100%, ±3%; 0-69%, unspecified;
	PR Measuring Range	30-240BPM.	30-235BPM.
	PR Resolution	1 bpm	1 bpm
	PR Accuracy	±1 bpm or ±1%, whichever is greater	±2 bpm (30-99bmp) ±1% (100-235bmp)
Testing	**Biocompatibility**	ISO 10993-5 and ISO 10993-10	ISO 10993-5 and ISO 10993-10
	Electrical Safety	IEC 60601-1 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-11
	Electromagnetic Compatibility	IEC 60601-1-2	IEC 60601-1-2
	Performance	ISO 80601-2-61	ISO 80601-2-61

8. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility evaluation：

The biocompatibility evaluation for the Pulse Oximeter C101H1 were conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The subject devices are made up of enclosure, button and finger clip. The finger clip will contact with patient skin. According to ISO 10993-1, the contacting classification is surface contacting and the

duration is intact skin contact less than 24 hours.

Electrical safety and electromagnetic compatibility (EMC):

Electrical safety and EMC testing were conducted on the Pulse Oximeter C101H1, consisting of all the modules and accessories in the system. The system complies with the IEC 60601-1:2005/A1: 2012, IEC 60601-1-11: 2015 and ISO 80601-2-61: 2011 standards for electrical safety and the IEC 60601-1-2:2014 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Performance Testing

- Pulse rate accuracy test
- Cleaning and disinfection cycle test

Clinical data:

The clinical trial was performed according to Clause 201.12.1.101.2 and Annex EE.2 of ISO 80601-2-61:2011 *Procedure for invasive laboratory testing on healthy volunteers.*

The purpose of the clinical trial was to evaluate the SpO2 accuracy performance of the C101H1 Pulse Oximeter during stationary (non-motion) conditions over a wide range of arterial blood oxygen saturation levels as compared to arterial blood CO-Oximetry. 12 healthy adult volunteer subjects (ages 22-27yr, with light to dark pigmentation) were included in the study conducted to evaluate the SpO2 accuracy performance of proposed devices. Each system was evaluated during steady state/non-motion conditions with various levels of induced hypoxia resulting in stable oxygen saturation levels between 100% and 70% SaO2. Arterial blood samples were drawn during simultaneous data collection from the test devices. The blood was immediately analyzed on reference CO-Oximetry providing functional SaO2 for the basis of the SpO2 accuracy comparison.

The SpO2 accuracy performance results showed the fingertip pulse oximeter to have an Arms of 2.12 during steady state conditions over the range of 70-100%.

Summary:

Based on the non-clinical and clinical performance as documented in the system development, the subject devices were found to substantially equivalent to the predicate device.

9. Conclusion

The non-clinical data support the substantial equivalence of the device and the hardware and software verification and validation demonstrate that the subject device should perform as intended in the specified use conditions. The clinical data demonstrate that the subject device performs comparably to the predicate

device that is currently marketed for the same intended use.