DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 22, 2016

AMEMO INC.
Hua Xie
CEO
1154 Cadillac Court
Milpitas, California 95035

Re: K153021
Trade/Device Name: Fingertip Pulse Oximeter A310
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: November 14, 2016
Received: November 14, 2016

Dear Hua Xie:

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 Industry and Consumer Education 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" (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 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153021

Device Name
Fingertip Pulse Oximeter A310

Indications for Use *(Describe)*
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.

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.

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Section III 510(K) Summary

Date: 2016-11-17

Sponsor:

AMEMO INC
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Contact person: Mr. Hua Xie
Email: Raymond691116@gmail.com

Proposed Device:

Model	Name
A310	Fingertip Pulse Oximeter

Trade Name: Fingertip Pulse Oximeter A310

Common Name: Fingertip Pulse Oximeter

Product Classification: DQA; 870.2700; Class II

Classification Panel: Anesthesiology

Predicate Device: MD300C1 Fingertip Pulse Oximeter (K093757)

Indications for use:

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.

Device description:
Fingertip Pulse Oximeter A310 is a battery powered device intended for use in

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measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR).

The Finger Pulse Oximeter works by applying a sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and photo detector. The one wavelength of light source is 660 nm, which is red light; the other is 940 nm, which is Infrared light. Skin, bone, tissue, and venous vessels normally absorb a constant amount of light over time. The photodetector in finger sensor collects and converts the light into electronic signal which is proportional to the light intensity. The arteriolar bed normally pulsates and absorbs variable amounts of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO2.

This equipment mainly composed of PCB board, On/Off button, mode button, OLED screen, battery compartment, and plastic shell.

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.

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Comparison list of the technological characteristics

Comparison Items		Applicant Device	Predicate Device (K093757)	Remark
Indications for use		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	Fingertip Pulse Oximeter MD300C1 is a portable non-invasive, spot-check, oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult and pediatric patient at home, and hospital (including clinical use in internist/surgery, Anesthesia, intensive care and etc). Not for continuously monitoring	Different①
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 bed are used to determine oxygen saturation and pulse rate.	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 bed are used to determine oxygen saturation and pulse rate.	Same
Specifications	**LED wavelength**	Red= 660 nm; Infrared=905nm	Red= 660 nm; Infrared=940nm	Different②
	Power source	2 AAA alkaline batteries.	2 AAA alkaline batteries.	Same

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	Display data	SPO2%; PR	SPO2%; PR	Same
	SpO2 Measuring Range	0%-100%	0%-100%	Same
	SpO2 Resolution	1%	1%	Same
	SpO2 Accuracy	70~100%, ±3%; 0-69%, unspecified;	70~100%, ±3%; 0-69%, unspecified;	Same
	PR Measuring Range	30-235BPM.	30-235BPM	Same
	PR Resolution	1 bpm	1 bpm	Same
	PR Accuracy	± 2 bpm (30-99bmp) 2% (100-235bmp)	± 2 bpm (30-99bmp) 2% (100-235bmp)	Same
Testing	**Biocompatibility**	ISO 10993-5 and ISO 10993-10	ISO 10993-5 and ISO 10993-10	Same
	Electrical Safety	IEC 60601-1 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-11	Same
	Electromagnetic Compatibility	IEC 60601-1-2	IEC 60601-1-2	Same
	Performance	ISO 80601-2-61	ISO 9919	Different③

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[Discussion]

The proposed device has the same application site, performance testing, and accuracy as the predicate device. The differences are

1. The predicate device is intended for both adult and pediatric patients in hospital and home environments, however Oximeter A310 is intended only for adult in hospital environments. Both applicable population and environment of A310 are smaller than the predicate, which will not raise different questions of safety or effectiveness compared to the predicate device. All A310's indications for use is Substantially Equivalent (SE) to the predicate device in its declared scope.

2. Infrared LED Wavelength of Oximeter A310 is 905nm, and predicate's wavelength is 940nm. These two wavelengths are both adopted widely in measurement of SPO2. This difference will affect the performance of the device, especially the accuracy. We conducted the ISO 80601-2-61 test to verify the performance and electrical safety of Oximeter A310, and the clinical evaluation to validate the accuracy of measurement. The clinical evaluation result shows that A310's accuracy complies with the requirement defined in the standard ISO 80601-2-61. All validation demonstrates that Oximeter A310 is substantially equivalent to the predicate device.

3. Application of the performance standard is different. The predicate device uses the ISO 9919 to demonstrate the performance. However, ISO 9919 has been withdrawn, and ISO 80601-2-61 is the newest international performance standard of oximeter, and state-of-the-art for the oximeter. And, ISO 80601-2-61 is also the Recognized Consensus Standards of FDA.

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Non-clinical testing summary:
The Fingertip Pulse Oximeter A310 was subjected to bench testing. The following non-clinical testing was performed to demonstrate substantial equivalence of A310 with its predicate. The test results demonstrated that the proposed device complies with the following standards and requirements:

IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and essential performance

IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

ISO 80601-2-61: Medical electrical equipment – Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.

IEC 60601-1-11: Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

FDA Guidance for Pulse Oximeters - Premarket Notification Submissions [510(k)s]

ISO 10993-5: Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity

ISO 10993-10: Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

Pulse Rate Accuracy testing has been performed by referring to the SpO2 simulator. Pulse rate accuracy was stated as the root-mean-square difference between paired pulse date recorded with A310 and simulator. The testing procedure and results are included in the report A310 Fingertip Pulse Rate Accuracy Test Report, which

includes the results of PR measurement range, resolution, and measurement accuracy. The report demonstrates that the PR accuracy complies with the declaration of specification at the normal condition.

The testing to verify the performance after simulated lifetime was conducted. The testing conducted included 1424 cycles of cleaning of the device according to the description in the operation manual. After the cycles of cleaning, the accuracy testing of SpO2 and PR was performed by referring to the SpO2 simulator. The testing result demonstrates that the device continues to perform within specifications after a simulated lifetime of use.

Clinical testing summary

The functional oxygen saturation (SpO2) measurement has been validated in accordance with ISO 80601-2-61. The clinical testing was completed on a total of 12 healthy adult volunteers (8 man and 4 women) with light to dark skin pigmentations in the range of 70% to 100% against a laboratory CO-Oximeter. The subjects include 6 people with medium skin, 1 with light skin, and 5 with dark skin pigmentation. Total 555 data points were sampled for analysis.

The measured arterial hemoglobin saturation value (SpO2) of the proposed device was compared with arterial hemoglobin oxygen (SaO2) value, determined from blood samples with a CO-oximeter. The accuracy of the device is in comparison with the CO-oximeter samples measured over the SpO2 range 70%-100%.

Accuracy data was calculated using the root-mean-squared (Arms value) for all subjects, per ISO 80601-2-61, the result showed that the error is far less than the scope specified in the standard; and the Agreement between Methods of Measurement with Multiple Observations per each subject was analyzed with the Bland and Altman statistics, the analysis demonstrated that the vast majority of data is within ±95% limit of agreement.

The SpO2 accuracy result showed that the root-mean-square (Arms) value of the Fingertip Pulse Oximeter is ±3% with the saturations from 70% to 100%. The following is the summary of the testing results:

Items	70-100	70-<80	80-<90	90-100
#pts	555	192	237	126
Bias	0.40	0.98	0.41	1.06
RMS	2.21	2.42	1.58	2.80

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In addition, there were no reported adverse effects during these investigations.

Conclusion:

The Fingertip Pulse Oximeter A310 has the same intended use, the same technology as the predicate device. Thus we conclude the subject device to be Substantially Equivalent to the predicate device.