April 27, 2020

LD Technology LLC
Albert MAAREK
Quality Manager
100 N. Biscayne Blvd Suite 502
Miami, Florida 33132

Re: K200141
Trade/Device Name: Oxi-W System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DQA
Dated: March 31, 2020
Received: April 1, 2020

Dear Albert MAAREK:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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
K200141

Device Name

Oxi-W system

Indications for Use *(Describe)*

Oxi-W system is intended for use:
To spot check or monitor Oxygen saturation of arterial hemoglobin (SpO2%) and pulse rate.
To analyze the pulse waveform (Photoplethysmography or PTG) provided by the oximeter. It only provides mathematical analysis of the input of the PTG using the first and second derivatives of the PTG values related to the microvascular condition.
To analyze the basic rhythms of the NN or RR intervals in heart rate from the PTG, both in the time domain and in the frequency domain (short time 5 minutes). It only provides mathematical analysis of the heart rate variability values related to the autonomic nervous system function.
The system only provides mathematical analysis of input PTG values. It is practitioner to make proper judgement based on these values.
The software provides a visual alarm for the values of the heart rate and/or SpO2 percent out of the normal range and for the bad quality signal transmission.
The data are stored in PC in the Backup system of the **Oxi-W** software. The device is intended use only for adult subjects (> 20 years old) This Oximeter is intended to be used in spot-checking (5 minutes).
The device is intended for use in licensed practitioner's office
This device is no intended to be used at home, in hospital or out-of-hospital transport
The device is not intended for use in support life and not for continuously monitoring
The system will be used by practitioner.

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)*

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510(k) Premarket Notification Number: date: April,17,2019

510(k) Summary
K200141

Oxi-W system

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

1. Submitter's Identification:

Manufacturer **:** L.D TECHNOLOGY
Address **:** 100 N. Biscayne Blvd, Suite 502 Miami, FL, 33132, USA
Tel **:** 305-379-9900
Email **:** albert.ldteck@gmail.com

2. Device Name / Classification

Trade name	: Oxi_W system
Device Common Name	: Cardiac Monitor
Regulation Number	: 21 CFR 870.2300
Product Codes	: MWI, DQA
Classification	: Class II
Classification Panel	: Anesthesiology

3. Predicate legally marketed devices

Primary Predicate Device	**:** LD-Oxi system cleared under K160956
Applicant	: LD Technology LLC .
Product codes	: MWI and DQA
Reference Device	:PC-60 NW Fingertip Oximeter cleared under K120502
Applicant	: Shenzhen creative industry Co .Ltd
Product code	: DQA

4. Device Description

The Oxi-W System is a programmable electro medical system (PEMS) including:

- Pulse oximeter with data transmission via Bluetooth.
- Software installed on a computer

Description of the features

Hardware :

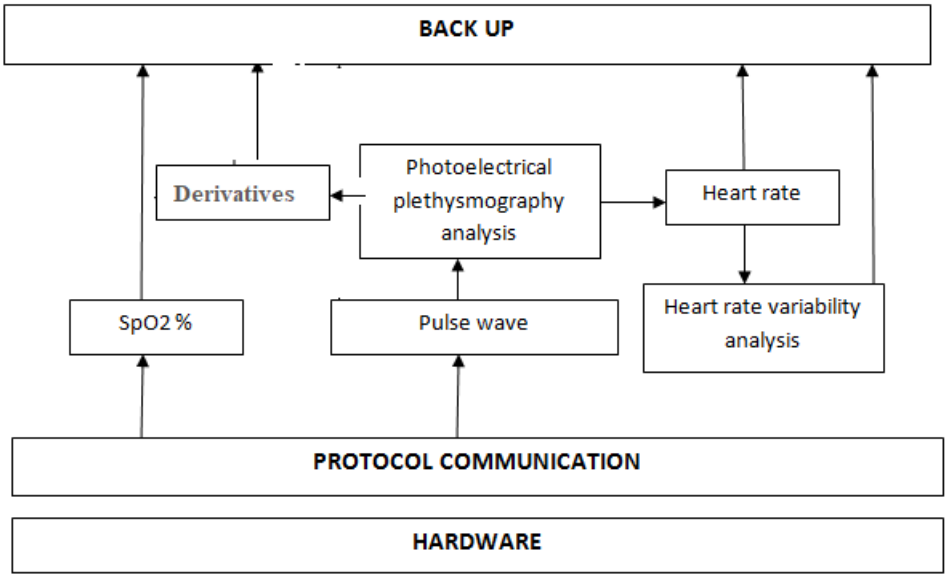
- collects SpO2%, pulse rate value and vertical bar graph pulse amplitude (photoplethysmography) and sends the encrypted numbers to the Software.

Software:

- Display SPo2%, and photoplethysmography.
- Mathematical analysis of the pulse waveform (Photoplethysmography) using the first and second derivative of the wave to provide values related to the microvascular condition.
- Mathematical analysis of the pulse waveform (Photoplethysmography) to detect the heart rate and provides values of the heart rate variability related to the autonomic nervous system function.

Software specifications

The system carries out the following operations:



5. Intended use and indications for use

Oxi-W system is intended for use:

To spot check or monitor Oxygen saturation of arterial hemoglobin (SpO2%) and pulse rate.

To analyze the pulse waveform (Photoplethysmography or PTG) provided by the oximeter. It only provides mathematical analysis of the input of the PTG using the first and second derivatives of the PTG values related to the microvascular condition.

To analyze the basic rhythms of the NN or RR intervals in heart rate from the PTG, both in the time domain and in the frequency domain (short time 5 minutes). It only provides mathematical analysis of the heart rate variability values related to the autonomic nervous system function.

The system only provides mathematical analysis of input PTG values. It is practitioner to make proper judgement based on these values.

The software provides a visual alarm for the values of the heart rate and/or SpO2 percent out of the normal range and for the bad quality signal transmission.
The data are stored in PC in the Backup system of the **Oxi-W** software.
The device is intended for use only for adult subjects (> 20 years old)
This Oximeter is intended to be used in spot-checking (5 minutes).
The device is intended for use in licensed practitioner's office
This device is no intended to be used at home, in hospital or out-of-hospital transport
The device is not intended for use in support life and not for continuously monitoring
The system will be used by practitioner.

6. Device specifications and comparison with predicate device.

6.1 Intended use and indication for use comparison

Specifications	LD-OXI system K k160956	Oxi-W system	Comparison
Intended use	To spot check or monitor Oxygen saturation of arterial hemoglobin (SpO2%) and pulse rate. To analyze the pulse waveform (Photoelectrical Plethysmography or PP) provided by the oximeter. It only provides mathematical analyses of the input of the SpO2 measurement. To analyze the basic rhythms of the NN or RR intervals in heart rate, both in the time domain and in the frequency domain (short time 5 minutes). It only provides mathematical analysis of the input of the heart rate variability. The mathematical analysis of Photoelectrical Plethysmography and HRV ARE NOT intended use for diagnosis. The software provides a visual alarm for the values of the heart rate and/or SpO2 percent out of the normal range and for the bad quality signal transmission. The data are stored in PC in the Backup system of the LD-Oxi software.	To spot check or monitor Oxygen saturation of arterial hemoglobin (SpO2%) and pulse rate. To analyze the pulse waveform (Photoplethysmography or PPG) provided by the oximeter. It only provides mathematical analysis of the input of the PTG using the first and second derivatives of the PTG values related to the microvascular condition. To analyze the basic rhythms of the NN or RR intervals in heart rate from the PTG, both in the time domain and in the frequency domain (short time 5 minutes). It only provides mathematical analysis of the heart rate variability values related to the autonomic nervous system function. The system only provides mathematical analysis of the input PTG values. It is the practitioner's responsibility to make proper judgement based on these values. The software provides a visual alarm for the values of the heart rate and/or SpO2 percent out of the normal range and for the bad quality signal transmission. The data are stored in PC in the Backup system of the Oxi-W software.	Difference (1)

Indication and Prescription for use	The device is intended use only for adult subjects (> 20 years old) This Oximeter is intended to be used in spot-checking (5 minutes) The device is intended use in licensed practitioner's office This device is no intended to be used at home, in hospital or out-of-hospital transport The device is not intended use in support life and not for continuously monitoring The system will be use by practitioner.	The device is intended for use only for adult subjects (> 20 years old) This Oximeter is intended to be used in spot-checking (5 minutes). The device is intended for use in licensed practitioner's office This device is no intended to be used at home, in hospital or out-of-hospital transport The device is not intended for use in support life and not for continuously monitoring The system will be used by practitioner.	Only grammatical corrections

6.2 Software specification and comparison with predicate device

Specifications	LD-OXI software K k160956	Oxi-W software	Comparison
Software measurements and Results	SpO2%, Pulse rate, Photoplethysmography, Heart rate variability analysis at rest and using Ewing tests , Photoplethysmography Second derivative analysis .	SpO2%, Pulse rate, Photoplethysmography, Heart rate variability analysis at rest and using Ewing tests , Photoplethysmography Second derivative analysis	Same
Data transmitted by the hardware	SpO2%, Pulse rate, Photoplethysmography,	SpO2%, Pulse rate, Photoplethysmography,	Same
Mode of data reception	USB port of the PC	Hardware Bluetooth microcontroller to PC	Difference (2).

6.3 Hardware specifications and comparison with reference predicate device.

Specifications	LD-OXI hardware k160956	PC-60NW k120502	Comparison
Scientific Background	Based on the red and infrared light absorption characteristics of oxygenated and deoxygenated hemoglobin.	Based on the red and infrared light absorption characteristics of oxygenated and deoxygenated hemoglobin.	Same
Material in contact with the patient	Reusable SPo2 probe Thermoplastic polyurethane (TPU) material and latex free	Reusable SPo2 probe Thermoplastic polyurethane (TPU) material and latex free	Same
Placement of the prove	Index finger	Index finger	Same
Classification	Class II	Class II	Same
Degree of protection against electric shocks	BF	BF	Same
Operating mode	Continuous use	Continuous use	Same

Features	To spot check or monitor Oxygen saturation of arterial hemoglobin, pulse rate and photoplethysmography for 5 minutes and transmission of the data to a software for mathematical analysis.	To spot check or monitor Oxygen saturation of arterial hemoglobin, pulse rate and photoplethysmography for 5 minutes and transmission of the data to a software for mathematical analysis.	Same
Power supply	Lithium battery 3.7 V rechargeable by USB port	2 x LR03 (AAA) alkaline batteries 3V	Difference (3)
IR light Wavelength	880nm +/- 10	890 nm +/- 10	Same , the small different does not change the reading according to the tolerance +/- 10
RED light Wavelength	660nm +/- 10	663 nm +/- 10	Same , the small different does not change the reading according to the tolerance +/- 10
Pulse rate (PR) Range	30~235 bpm	30~235 bpm	Same
PR Accuracy	±3	±3	Same
SpO2% accuracy	70%~100%:±2% , 0~69%,unspecified	70%~100%:±2% , 0~69%,unspecified	Same
Data transmission	USB	Bluetooth	Difference(4)
Standard met	60601-1 3rd Ed 60601-1-2 3rd Ed ISO 80601-2-61	60601-1 3rd Ed 60601-1-2 3rd Ed ISO 80601-2-61	Same
Module oximeter Circuit board and components	OEM (K090671) USB microcontroller Circuit board integrated to the probe	OEM (k120502) Bluetooth microcontroller (Soc) Circuit board integrated to the probe	Difference (5) for the microcontroller.
Data transmission Speed	19200 Bauds	19200 Bauds	Same

7. Substantial equivalence

Predicate legally marketed device

LD-Oxi system K k160956 Applicant: LD Technology LLC. Product code MWI, DQA

Similarities:

- ✓ Has the same intended and indication for use (I.e. details analysis of the intended use writing),
- ✓ Same technological characteristics as the predicate device
- ✓ Same safety and effectiveness
- ✓ Has the same material in contact with the patient
- ✓ Do not affect the Fundamental Scientific Technology
- ✓ Do not change the prescription use

Differences:

Difference (1) The new writing of the intended use is NOT a change or a new intended use, it is only to clarify the reading of the intended use and the utility of the device.

The sentence “To analyze the pulse waveform (Photoelectrical Plethysmography or PP) provided by the oximeter. It only provides mathematical analyses of the input of the SpO2 measurement”.
Was replaced by :
To analyze the pulse waveform (Photoplethysmography or PPG) provided by the oximeter. It only provides mathematical analysis of the input of the PPG using the first and second derivatives of the PTG values related to the vascular microcirculation condition.
Reason of replacement:

a) The word Photoplethysmography or PPG is used in peer reviews regarding the technology and therefore, it is commonly understood by the user.
b) The sentence “mathematical analyses of the input of the SpO2 measurement” is not clear. In fact, the software performs a mathematical analysis of the pulse waveform (PPG) and not of the SPo2 measurement. The mathematical analysis provides the second derivative PPG and the software results come from the detected points (a,b,c,d and e) of the second derivative PPG.
Therefore, the mathematical analysis will be better understood by the users.
c) Adding “related to the microvascular condition” is NOT a new intended use, it only clarifies the utility of the performed mathematical analysis of the second derivative PPG.

The sentence “It only provides mathematical analysis of the input of the heart rate variability”.
Was replaced by:
It only provides mathematical analysis of the heart rate variability values related to the autonomic nervous system function.
Reason of replacement:
Adding “related to the autonomic nervous system function” is NOT a new intended use: it only clarifies the utility of the performed mathematical analysis of the heart rate variability

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The sentence “The mathematical analysis of Photoelectrical Plethysmography and HRV ARE NOT intended use for diagnosis.”
Was replaced by:
The system only provides values. It is the practitioner’s responsibility to make proper judgements based on these values.
Reason of replacement:
The device provides values related to the autonomic nervous system function and microvascular condition. These values are not intended to provide diagnosis, but only allow the practitioner to judge how those values will be used in the practice.

Difference (2) Mode of Data reception (Bluetooth vs USB)
Difference (3) Power supply 2 x LR03 (AAA) alkaline batteries 3V vs USB port
Difference (4) and (5) Data transmission Bluetooth versus USB using different microcontrollers.

8. Performances and Effectiveness General safety concerns.

Clinical Test:

Since the Oxi_W algorithms and hardware have the same intended use and results as the predicate device, the Oxi-W does not require clinical tests since the predicate device does not provide any clinical Test.

Oxi_W testing:

1. Laboratory tests

- IEC 60601-1:2005 + CORR.1 (2006) + CORR.2 (2007) + AM1 (2012), Medical Electrical Equipment -- Part 1: General Requirements For Basic Safety And Essential Performance.
- IEC 60601-1-2: 2007, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility -Requirements And Tests.
- ISO 80601-2-61:2011 - Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.

2. CRC (Cyclic redundancy check) Coding was performing to demonstrate the software performance to accurately capture, store, and analyze the data measured by the hardware
3. Calibration tests (simulator oximeter)
4. Software verification and validation(SRS/SDS/STD/STR)
5. Bluetooth testing and cybersecurity risk analysis according to the FDA Wireless Guidance (2014), Cybersecurity Guidance (2013) and Design of Bluetooth version 4.0 white paper and FDA released a Safety Communication on March 3,2020.

Difference discussion:

Difference (1) is only to clarify the reading of the intended use and the utility of the device and does not affect the performances and effectiveness and General safety concerns of the proposed device.

Difference (2) requires Software New protocol communication.

The new protocol communication has been verified and validated by the software verification and validation(SRS/SDS/STD/STR) and CRC coding and therefore, does not affect the performances and effectiveness and General safety concerns of the proposed device

Difference (3) regarding the Power supply 2 x LR03 (AAA) alkaline batteries 3V vs USB port Will reduce the risk during the shipping and therefore, does not affect the performances and effectiveness and General safety concerns of the proposed device

Difference (4) and (5) Data transmission Bluetooth versus USB using different microcontrollers. may increase the risk of interference and cybersecurity. The risk of interference and cybersecurity has been tested and evaluated according to according to the FDA Wireless Guidance (2014), Cybersecurity Guidance (2013) and Design of Bluetooth version 4.0 white paper and FDA released a Safety Communication on March 3,2020 and the difference 4 and 5 do not affect the performances and effectiveness and General safety concerns of the proposed device

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Therefore, the proposed device using a different cleared hardware than the predicate device does not affect its performance, safety, and effectiveness.

Conclusions

In conclusion, the proposed device, Oxi-W system, has the same intended use, and similar technological characteristics compared to the predicate device. The difference in technological characteristics are addressed by performance testing, and do not raise different questions of safety and effectiveness.

Signature:

Albert MAAREK

Premarket notification [510K] Number: k200141