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

July 6, 2016

LD Technology LLC
Albert Maarek
Quality Manager
100 N. Biscayne Blvd, Suite 500
Miami, Florida 33132

Re: K160956
Trade/Device Name: LD-Oxi 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: June 3, 2016
Received: June 6, 2016

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. 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.

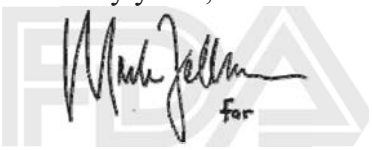
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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 K160956

Device Name

LD-Oxi- system

Indications for Use *(Describe)*

LD-Oxi system is intended for 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. 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.

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)*

L.D Technology LLC.

Special 510(k) Premarket Notification Number: Preparation date: March 2, 2016

510(k) Summary
LD-Oxi 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
Owner of LD Technology: MAAREK Albert
Address:
L.D Technology
100 N.Biscayne Blvd, Suite 502
Miami, FL, 33132, USA
Tel: 305-379-9900
Email: albert.ldteck@gmail.com

2. Device Name / Classification
LD-Oxi System
System components:
21 CFR 870.2300
21 CFR 870.2700
Product Codes: MWI and DQA.
Classification: Class II
Classification Panel: Cardiovascular /Anesthesiology

3. Predicate legally marketed device
Electro Sensor Oxi (ESO) K102442 Applicant: LD Technology LLC
Product codes: MWI and DQA

4. Device Description
The LD-Oxi System is a programmable electro medical system (PEMS) including:

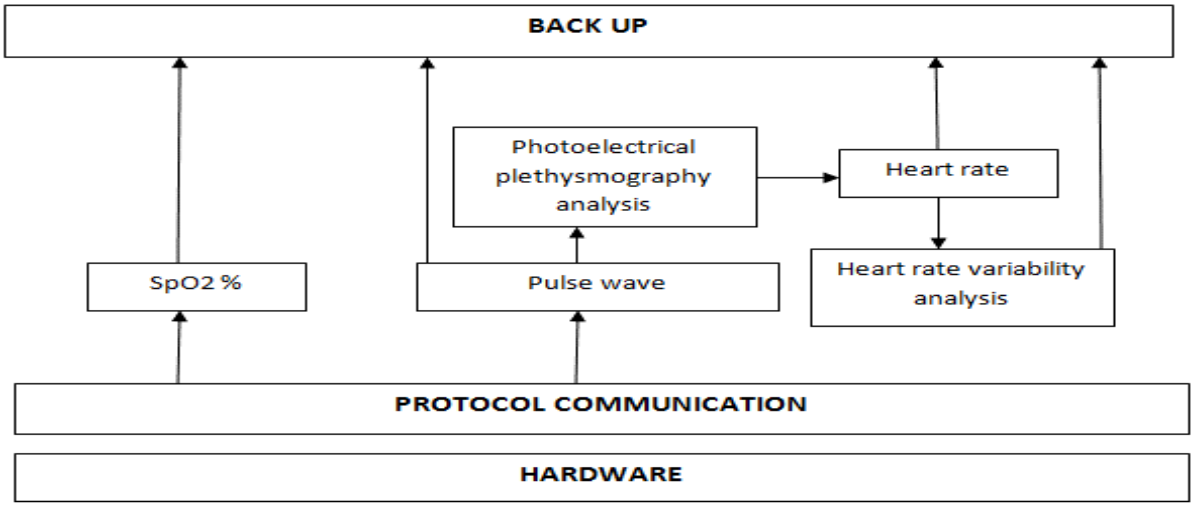
- USB plug and play Pulse oximeter device including an electronic circuit and reusable Adult SpO2 probe
- Software installed on a computer

Description of the features

- Displays SpO2%, pulse rate value and vertical bar graph pulse amplitude (photoplethysmography).
- Mathematical analysis of the pulse waveform (photoelectrical Plethysmography feature).
- Mathematical analysis of the Heart Rate Variability (HRV feature).

Software specifications

The system carries out the following operations:



5. Intended use and indications for use

LD-Oxi system is intended for 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. 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 not 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 used by practitioner.

6. Device specifications and comparison with predicate device

Specifications	ESO	LD-Oxi
	SIMILARITIES	
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	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

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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 used by practitioner.	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 used by practitioner.
Material in contact with the patient	Reusable SPo2 probe PTU latex free	Reusable SPo2 probe PTU latex free
Scientific Background	Based on the red and infrared light absorption characteristics of oxygenated and deoxygenated hemoglobins.	Based on the red and infrared light absorption characteristics of oxygenated and deoxygenated hemoglobins.
Placement of the prove	Index finger	Index finger
Power supply	5V (power supply by USB port)	5V (power supply by USB port)
Classification	Class II	Class II
Degree of protection against electric shocks	BF	BF
Operating mode	Continuous use	Continuous use
IR light features		
Wavelength: Radiant Flux: Spectral Bandwidth: Forward Voltage: Reverse Voltage:	905 $\pm$10 nm 2.0mW 50nm 1.7V 5V	880nm $\pm$10 nm 6.75mW 50nm 1.7V 5V
RED light features		
Wavelength: Radiant Flux: Spectral Bandwidth: Forward Voltage: Reverse Voltage:	660nm$\pm$2nm 1.8mW 25nm 2.4V 5V	660nm $\pm$2nm 6.65mW 25nm 2.4V 5V
Pulse wave		
Resolution	1%	1%
Signal Strength	0-15	0-15
Bargraph	0-15	0-15
Plethysmogram	0 – 100, auto-gained for highest resolution	0 – 100, auto-gained for highest resolution
Pulse rate		
Measuring NO Alarm Range	30~235 bpm	30~235 bpm
Resolution	1pbm	1pbm

Serial Communication Logic Levels	3.3V CMOS voltage levels	3.3V CMOS voltage levels
Voltage	+3.3 ± 0.17 V DC	+3.3 ± 0.17 V DC
Average Current	15mA	15mA
DEVICE MODIFICATIONS		
Standard met	60601-1 2nd Ed 60601-1-2 2nd Ed ISO 9919	60601-1 3th Ed 60601-1-2 3th Ed ISO 80601-2-61
Module oximeter Circuit board	OEM from Beijing Choice Electronic Technology Co. Ltd.(MD300I k072825)	OEM from Contec medical Ltd (CMS50 E K090671)
Circuit board size	128 (L) x 143 (W) x 33 (H) mm	57(L) × 32(W) × 30 (H) mm
Circuit board weight	1.2 Kg	50 g
Data transmission Speed	4800 Bauds	19200 Bauds
Probe connection	LEMO	NELLCOR
Mathematical analysis of the heart rate	At rest	At rest and during Ewing tests

7. Contra-indications

- **Patients undergoing external defibrillation**
- Patients connected to electronic life support devices, or any implanted electronic device.
- Do not use this device in the presence of magnetic resonance imaging (MR or MRI) equipment. MRI equipment may cause induced current to the SpO2 sensor resulting in patient injury.
- This device should not be used on pregnant women. The effects on the fetus, as well as accuracy of readings are unknown.
- When using the finger probe, utilize the arm not in use for blood pressures, arterial lines, or having an AV fistula or pressure dressing.
- Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, and fluorescein
- Significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin or methhemoglobin, will affect the accuracy of the SpO2 measurement.
- Any condition that restricts blood flow, such as use of a blood pressure cuff or extremes in systemic vascular resistance, may cause an inability to determine accurate pulse rate and SpO2 readings
- Operation of this device may be adversely affected in the presence of strong electromagnetic sources, such as electro surgery equipment.
- Operation of this device may be adversely affected in the presence of computed tomography (CT) equipment.
- Do not use this device in the presence of flammable anaesthetics; a spark hazard exists which may result in explosion.
- Fingernail polish or false fingernails: Fingernail polish or false fingernails may cause inaccurate SpO2 readings.

8. Undesirable side effects:
Side effects or adverse reactions are none known to date.

9. Substantial equivalence
Predicate legally marketed device
Electro Sensor Oxi K102442 Applicant: LD Technology LLC. Product code MWI

Similarities:
- ✓ Same intended use
- ✓ Same technological characteristics as the predicate device
- ✓ Same safety and effectiveness

New characteristic:
- ✓ Size and weight of the circuit board
- ✓ Data transmission speed (Baud)
- ✓ Probe connection
- ✓ Additional mathematical analysis of the heart rate variability during tests.
- ✓ Updated standards

10. Performances and Effectiveness

1. Calibration tests (simulator oximeter)
2., Software verification (SRS/SDS/STD/STR/ Software algorithms tests with input data from the MIT-BIH database)
4. Peer reviews for the photoelectrical plethysmography mathematical analysis.
5. Peer review reference for the heart rate variability mathematical analysis.

The new characteristics:
- ✓ Size and weight of the circuit board
- ✓ Data transmission speed (Baud)
- ✓ Probe connection
- ✓ Addition mathematical analysis of the heart rate variability during tests.
- ✓ Updated standards

Do not affect the performances and effectiveness of the modified device

11. General Safety Concerns
I.e.-LD-Oxi Risk management
The new characteristics:
- ✓ Size and weight of the circuit board
- ✓ Data transmission speed (Baud)
- ✓ Probe connection
- ✓ Addition mathematical analysis of the heart rate variability during tests.
- ✓ Updated standards

Do not affect the general safety of the modified device as shown by the laboratory testing using the updated standards

12. Standards

- ✓ IEC 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. Third Edition December 2006
- ✓ IEC60601-1-2: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests. Third Edition 05/17/2007
- ✓ IEC 80601-2-61: Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of oximeters. 04/11/2011
- ✓ Guidance for: Industry; FDA staff; and Content of Premarket Submissions for Software Contained in Medical Devices Document issued on: May 11, 2005
- ✓ ISO 14971: Medical devices — Application of risk management to medical devices. March 01 2007

Conclusions

LD-Oxi is equivalent in performances, technology, safety and efficacy to the legally marketed predicate device.

Signature:

Albert MAAREK

Premarket notification [510K] Number: k160956