SEP 10 2010

L.D Technology LLC.

510(k) Premarket Notification Number: Preparation date: July, 02 2010

510(k) Summary
Electro Sensor Oxi / E.S.O

Name of the device: Electro Sensor Oxi
Common name: E.S.O
Pulse oximeter/Photoelectrical Plethysmograph/Heart Rate variability
Regulation number:
21 CFR 870 2700 Product Code: DQA
Classification: Class II
Classification Advisory: Cardiovascular/Anesthesiology

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
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2. Device Name / Classification
Electro Sensor Oxi
System components :
21 CFR 870 2700 Product Code: DQA
Classification: Class II
Classification Panel: Cardiovascular /Anesthesiology

3. Predicate legally marketed device
Electro Sensor Teck (Model PEMS) K083229 Applicant: LD Technology LLC Product code MW.
4. Device Description
The E.S.O System is a programmable electro medical system (PEMS) including:

- USB plug and play hardware device including an electronic box 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.
- Mathematical analysis of the pulse waveform (photoelectrical Plethysmograph' feature).
- Mathematical analysis of the Heart Rate Variability (HRV 'feature).

5. Intended use and indications for use

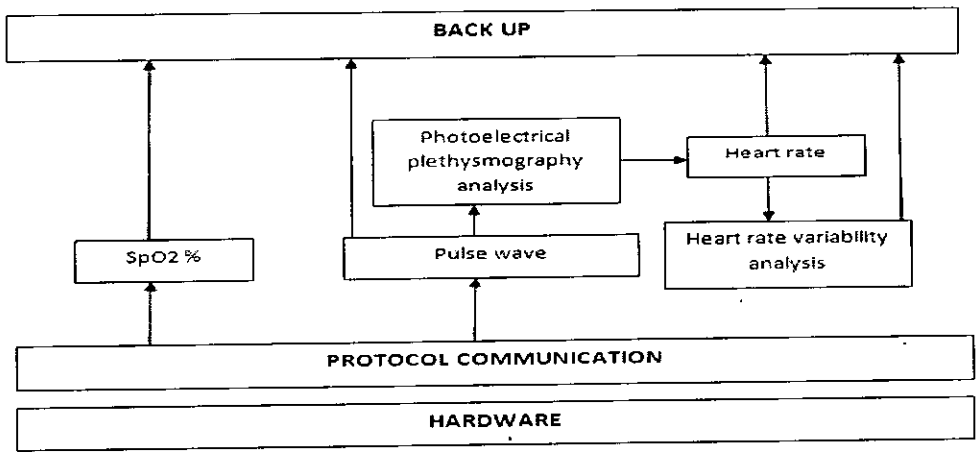
- To spot check or monitor Oxygen saturation of arterial hemoglobin (SpO2%) and pulse rate.
- To analyze the pulse waveform (Photoelectrical Plethysmography or PP) provided by the oximeter. It only provides mathematical analyses of the input of the SpO2 measurement.
- To analyze the basic rhythms of 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 analyses 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 ES Teck software.
The device is intended use only for adult subjects (> 20 years old)
This Oximeter is intended to be used in spot-checking (2 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.

6. Performances, specifications and materials
Technical specifications I.e. Device description

Software specifications

The system carries out the following operations:



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 carboxyhemoglogin 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 Teck (Model PEMS) K083229 Applicant: LD Technology LLC. Product code MWI

Similarities:

Substantial equivalence

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

New characteristic:

- ✓ The Heart rate detection comes from the oximeter wave form analysis (a/a from SDPTG) and not from the EKG device.

I.e. Tables of comparison of the E.S.O and E.S Teck and SE discussion: i.e. Executive summary

11. Performances and Effectiveness

1. Calibration tests (simulator oximeter)
2. The OEM subcontractor provided the oximeter, sensor, cable connections and software code source and they were cleared for use together.
3. 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.

Discussion of Clinical Test performed for the E.S.O:
Since the ES Teck do not required clinical tests.
The HRV and photoelectrical plethysmography analysis are only mathematical analysis and have not been approved by FDA for a specific clinical diagnosis in any device, so that is for reference only, therefore, no clinical validation is required for E.S.O.

Use of the published clinical investigations of the photoelectrical plethysmography and HRV mathematical analysis:
For interpretation of the results we use some published clinical investigations. These clinical investigations had been made with materials using the same technology (Pulse oximeter) and the same anatomical site (fingertip).

The fact to detect the heart rate from the oximeter wave form analysis and not from the EKG module does not affect the performances and the effectiveness of the E.S.O as shown by the peer review and comparative testing between EKG RR intervals (from predicate device) and SPo2 RR intervals (from E.S.O) in one hand, and in second hand, comparative HRV analysis results from the predicate device and E.S.O.

12. General Safety Concerns

The fact to remove the EKG PCB does not change the general safety to the legally marketed predicate device as shown in the laboratory tests reports of the E.S.O. system (IEC 60601-1-2 and IEC 60601-1-1).

13. Standards

AAMI EC57-1998(R) 2003 Testing and Reporting Performance Results of Cardiac Rhythm and ST-Segment Measurement Algorithms
IEC60601-1-1 Issued: 2000/12/14 Ed: 2 Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
IEC 60601-1-2 Issued: 2001/09/30 Ed: 2 Medical Electrical Equipment Part 1-2: General Requirements for Safety Collateral Standard: Electromagnetic Compatibility - Req. and Tests – Including Section 6 manual review
ISO9919 (From OEM subcontractor) Issued: 2005/03/15 Ed: 2 Medical electrical equipment Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use

Conclusions
E.S.O is equivalent in performances, technology, safety and efficacy to the legally marketed predicate device.

Signature:

Albert MAAREK

Premarket notification [510K] Number: K102442

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

L.D. Technology, Inc.
c/o Mr. Mark Job
Regulatory Technology Services, LLC
Responsible Third Party Official
1394 25th Street, NW
Buffalo, Minnesota 55313

SEP 10 2010

Re: K102442
Trade/Device Name: E.S.O. (Electro Sensor Oxi)
Regulatory Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II (two)
Product Code: 74 DQA, MWI
Dated: August 25, 2010
Received: August 26, 2010

Dear Mr. Job:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K102442

510(k) Number: K102442

SEP 10 2010

Device Name: E.S.O (Electro Sensor Oxi)

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102442