K083229

L.D Technology LLC.

FEB 2 3 2009

510(k) Premarket Notification Number: K083229
Preparation date: October, 16 2008

510(k) Summary
Electro Sensor Teck / ES Teck

Name of the device: Electro Sensor Teck Model PEMS
Common name:
E.S Teck
Heart Rate variability/Pulse oximeter/Photoelectrical Plethysmograph
Regulation number:
21 CFR 870.2340 Product Code: DPS
21 CFR 870 2700 Product Code: DQA
21CFR870.2780 Product Code: JOM
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
Owner of LD Technology: MAAREK Albert
Address:
L.D Technology
100 N.Biscayne Blvd, Suite 500
Miami, FL, 33132, USA
Tel: 305-379-9900
E mail: albert.ldteck@gmail.com

Contact Information:
Consultant and reviewer
Richard Clement MD
11459 NW 34 Street Miami FL 33178
Tel: 305-594-2145
Fax: 305-594 2174
Email: richardclementmd@yahoo.com
Date of Preparation: September, 20, 2008

2. Device Name / Classification
Electro Sensor Teck system
System components :
21 CFR 870.2340 Product Code: DPS
21 CFR 870 2700 Product Code : DQA
21CFR870.2780 Product Code JOM
Classification: Class II
Classification Panel: Cardiovascular /Anesthesiology

3. Predicate legally marketed devices
Readmyheart (Model RMH 3.0) K050620 HRV module Applicant: DailyCare BioMedical Inc.
Pulse Oximeter MD 300 I, K072825 Applicant: Beijing Choice Electronic Technology Co., Ltd.
Mc Pulse Photoelectric Plethysmograph K023238 Applicant: Meridian Co., Ltd.

4. Device Description
Description of the features

The ES Teck System is a programmable electro medical system (PEMS) including:

- USB plug and play hardware device including an electronic box , 3 disposable electrodes, reusable Adult SpO2 probe and reusable cables
- Software installed on a computer.

E.S Teck system is a combination of 2 devices (or modules) with specific features controlled by unique software:

- **Pulse Oximeter** displays SpO2%, pulse rate value and vertical bar graph pulse amplitude. The photoelectrical Plethysmograph' feature (PP) analyzes the pulse waveform provided by the oximeter.
- **HRV (Heart Rate Variability)** evaluates the variation of the heart rate, both in the time domain (statistical methods) and in the frequency domain (spectral analysis). Each QRS complex is detected and the so-called normal-to-normal (NN) or Rate-to-Rate (RR) intervals between adjacent QRS complexes are resulting from sinus node depolarization.

5. Intended use and indications for use
Each module has specific feature and intended use

1. Pulse Oximeter:
   - 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.

2. Heart rate variability (HRV) :
   - 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 licensed practitioner.

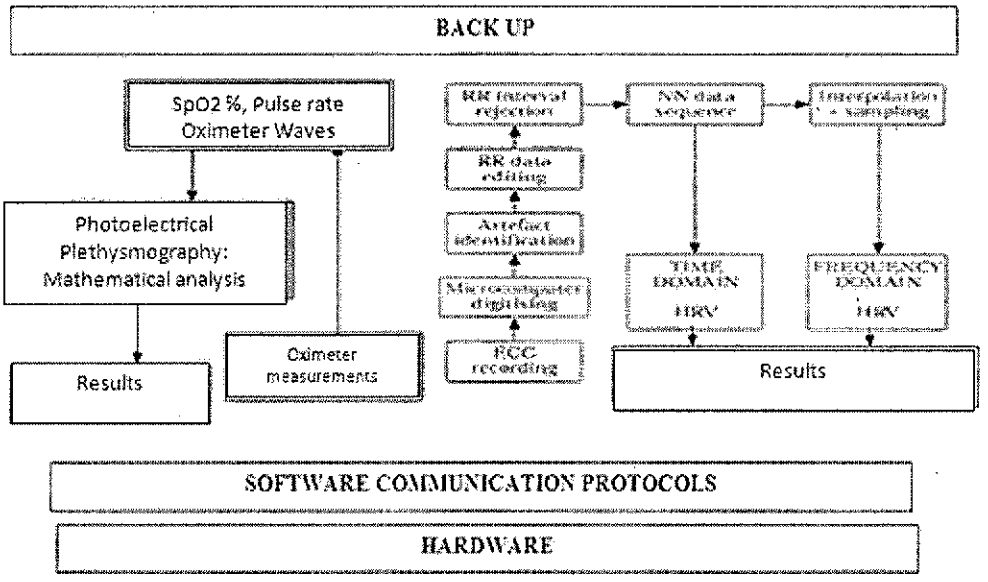
6. Performances, specifications and materials

Technical specifications

I.e. Device description

Software specifications

The system carries out the following operations:



7. Contra-indications

- **Patients undergoing external defibrillation**
- Anyone with erratic, accelerated or mechanically controlled irregular heart rhythms;
- Arterial fibrillation/flutter;
- Atrio-ventricular block;
  This device should not be used in association with or presence of cardiac pacemakers, 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 devices
Readmyheart (Model RMH 3.0) K050620 HRV module (checkmyheart) Applicant: DailyCare BioMedical Inc.
Pulse Oximeter MD 300 I, K072825 Applicant: Beijing Choice Electronic Technology Co., Ltd.
Mc Pulse Photoelectric Plethysmograph K023238 Applicant: Meridian Co., Ltd.

Similarities:
Substantial equivalence
For each module of the ES Teck
- ✓ Same intended use
- ✓ Same technological characteristics as the predicate devices
- ✓ Same safety and effectiveness

Differences:
- ✓ The entire intended uses of the ES Teck represent the intended uses of 3 predicate devices : the Combination devices does not affect the Class (II) of the device and the classification panel should be Cardiology/Anesthesiology
- ✓ The power is supplied from the USB port of the PC
- ✓ No LCD display, results in the PC monitor.
- ✓ The transmission of the data's are from the USB port of the PC
- ✓ The ES Teck HRV module does not be tested for the 60601-2-47, because the device is not ambulatory.
- ✓ The intended use of the ES Teck HRV module is out of the scope of the 60601-2-25 and 60601-2-51.

K083229

The Predicate legally marketed device Readmyheart is also a combination of devices including ECG and HRV module (Checkmyheart. i.e.IFU about the device). The IEC/ 60601-2-25 and IEC/ 60601-2-51 tests have been made for the ECG module and not for the HRV module.
I.e. Tables of comparison of the ES Teck modules and SE discussion: i.e. Executive summary

11. Performances and Effectiveness

HRV module:
1. Tests with input data from the MIT-BIH database
2. Calibration tests (simulator)
3. Software verification (SRS/SDS/STD/STR)
4. Peer review reference (Task Force of The European Society of Cardiology and The North American Society. European Heart Journal (1996) 17, 354–381)

Discussion of Clinical Test performed for the HRV module:
Since the HRV parameters algorithm and hardware are exactly the same as in the predicate device, The HRV module of ES Teck do not required clinical tests.
Instead, we conducted a simulator and MIT database comparison study for the function of heartbeat detection. Furthermore, HRV is only the mathematical analysis of heart beat has not been approved by FDA for a specific clinical diagnosis in any devices, so that is for reference only, therefore, no clinical validation is required for HRV module.

SpO2 module: (OEM contract)
1. Clinical tests of the OEM subcontractor
2. Calibration tests of the oximeter (simulator)
3. Software verification (SRS/SDS/STD/STR)
4. The OEM subcontractor provided the oximeter, sensor, cable connections and software code source and they were cleared for use together.

Photoelectrical Plethysmography application
1. Peer reviews algorithms and published clinical investigations
2. Software verification (SRS/SDS/STD/STR)

Discussion of Clinical Test performed for the Photoelectrical Plethysmography application:
Since the Photoelectrical plethysmography (PP) algorithms and hardware design are exactly the same as in the predicate device, The PP application of ES Teck do not required clinical tests. Furthermore, the PP application is only the mathematical analysis of Pulse wave of the oximetry, and has not been approved by FDA for a specific clinical diagnosis in any devices, so that is for reference only, therefore, no clinical validation is required for PP application.

Use of the published clinical investigations of the PP application:
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 facts:

- ✓ To use a combination devices
- ✓ To use unique software for analysis
- ✓ To use the USB connection for the power supply and the data transmission
- ✓ To display the results in the PC monitor and not in LCD
- ✓ No ambulatory device

Do not affect the performances and the effectiveness of the ES Teck system.

12. General Safety Concerns

The facts:

- ✓ To use a combination devices
- ✓ To use unique software for analysis
- ✓ To use the USB connection for the power supply and the data transmission
- ✓ To display the results in the PC monitor and not in LCD
- ✓ No ambulatory device

Do not change the general safety to the legally marketed predicate devices as shown the laboratory tests reports. (IEC 60601-1-2 and IEC 60601-1-1)

13. Standards

AAMI EC53:1995 (R) 2001 reaffirmed 11 May 2001 ECG cables and leadwires
AAMI EC57-1998(R) 2003 Testing and Reporting Performance Results of Cardiac Rhythm and ST-Segment Measurement Algorithms
ANSI/AAMI EC12:2000/(R) 2005 Disposable ECG electrodes
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 Teck is a combination devices and equivalent in performances, technology, safety and efficacy to the legally marketed predicate devices

Signature:

Albert MAAREK

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

LD Technology, LLC
c/o Dr. Richard Clement, M.D.
11459 NW 34 Street
Miami, FL 33178

FEB 2 3 2009

Re: K083229
Trade/Device Name: Electro Sensor Teck Model PEMS 1
Regulation Number: 21 CFR 870.2300
Regulation Name: Patient Physiological Monitor (without arrhythmia detection or alarms)
Regulatory Class: Class II
Product Codes: MWI, DPS, DQA, JOM
Dated: February 4, 2008
Received: February 18, 2008

Dear Dr. Clement:

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 such 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Bochner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number: K083229

Device Name: E.S Teck (Electro Sensor Teck)

Indication For Use:

Each module has specific feature and intended use

1. Pulse Oximeter:
   - 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.
2. Heart rate variability (HRV) :
   - 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 licensed practitioner.

Prescription Use ✓ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K083229