L.D Technology LLC.

510(k) Premarket Notification Number: K113264
Preparation date: September, 21 2011

510(k) Summary
Electro Sensors Complex Software (ES Complex Software)

Name of the device: Electro Sensors Complex Software
Common name: ES Complex Software

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
Quality Control and designer: 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

2. Device Name / Classification
Electro Sensors Complex Software (ES Complex Software) Class II
System components:
Regulation number:
21 CFR 8701130: Non Invasive Blood pressure measurement system, Class II
21 CFR 870 2700: Oximeter, Class II
21 CFR 882 1540: Galvanic Skin responses device Class II
21 CFR 870 2770: Analyzer Body Composition Class II
21 CFR 862 2100: Calculator/data processing module for clinical use, Class I
Product Code: NXD, DQA, GZO, MNW
Classification: Class II
Classification Panel: Cardiology/Neurology

3. Predicate legally marketed devices
   • Health care system software K110948. Applicant: TaiDoc Technology Corporation. Product codes NBW, DXN, FLL
4. Device Description
ES Complex Software is an optional software accessory for use with the following models with management capabilities: a) Contec 08A, blood pressure device b) ESO, oximeter c) EIS-GS, galvanic skin response device and d) ES-BC. Analyzer body composition
When use combination Contec 08A and ESO, and/or EIS-GS and/or ES-BC, the ES Complex software uploads the data of the 4 devices and displays the data into a computer for enhanced data management.

Description of the features

- Upload data:
  - ESO data: Patient stats, calculation and Historical Tracking of: SpO2 %, Wave value, Signal Strength, b/a, c/a, d/a, e/a, oximeter wave form in coding digits, Heart Rate (HR), Mean values of RR intervals, Maximum values (Mx), Minimum values (Mn), MxDMn HIB, SDNN, RMSSD, NN50 count, pNN50 %, VLF, LF, HF and LF/HF ratio.
  - EIS-GS data: Patient stats, measurement and Historical Tracking of: the conductance values of 22 skin pathways
  - ES-BC data: Patient stats, calculation and Historical Tracking of: Actual Impedance, Actual Phase Angle (PA), Estimated Body Fat (FAT), Estimated Fat Free Mass (FFM), Estimated Total Body Water (TBW), Estimated Intra-Cellular Water (ICW), Estimated Extra-Cellular Water (ECW), Estimated Basal Metabolic Rate (BMR), Estimated Daily Energy Expenditure (DEE) and actual Body Mass Index (BMI)
  - Contec 08A data: Patient stats, measurement and Historical Tracking of: Systolic and diastolic pressure

- Data management

5. Intended use and indications for use

ES Complex Software is an optional software accessory for use with the following models with data management capabilities: a) Contec 08A, blood pressure device b) ESO, oximeter c) EIS-GS, galvanic skin response device and d) ES-BC. Analyzer body composition
When use Contec 08A and ESO and/or EIS-GS and/or ES-BC, the ES Complex software uploads the data of the devices and displays the data into a computer for enhanced data management. The ES Complex software is intended for use in clinical settings as an aid for health care professionals to review, analyze and evaluate the historical tests results.
6. Specifications and performances

Software specifications
- Hardware platform: Laptop or PC based workstation (Intel architecture)
- Operating system: Windows 7
- Use of Off-the-Shelf software: Windows 7, MedCalc and Microsoft Office Word (v.2007 or 2010)
- Language: C++
- Microsoft Visual C++ compiler requirements: 2 Gb free space
- Program size requirements: 27 Mb

Software performances

7. Substantial equivalence
Predicate legally marketed devices
- Health care system software K110948. Applicant: TaiDoc Technology Corporation. Product codes NBW, DXN, FLL

The substantial equivalence with the Heath care system software K110948 is based upon:
- The same intended use and
- Different uploaded data, and the information submitted;
  a. Does not raise new questions of safety and effectiveness; and
  b. Demonstrates that the device is at least as safe and effective as the legally marketed device.
## 8. Table of comparison

### Table of comparison Health care system software K110948 / ES Complex Software

<table>
<thead>
<tr>
<th>Name device (510k number)</th>
<th>Health care system software K110948</th>
<th>ES Complex Software : uploaded data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intended use</strong></td>
<td>Health care system software is an optional software accessory for use with the following models with data management capabilities: a) Clever Check blood glucose meter b) Clever Check blood glucose and blood pressure monitors and c) Clever blood pressure monitors. When use with one of these device, Health care system software transfers data from the device’s memory into a computer for enhanced data management. The Health Care System Software is intended for use in home and clinical settings as an aid for users and their health care professionals to review, analyze and evaluate the historical test results to support health management effectively.</td>
<td>ES Complex Software is an optional software accessory for use with the following models with data management capabilities: a) Contec 08A, blood pressure device b) ESO, oximeter c) EIS-GS, galvanic skin response device and d) ES-BC. Analyzer body composition. When use Contec 08A and ESO and/or EIS-GS and/or ES-BC, ES Complex software uploads the data of the devices and displays the data into a computer for enhanced data management. The ES Complex software is intended for use in clinical settings as an aid for health care professionals to review, analyze and evaluate the historical tests results.</td>
</tr>
</tbody>
</table>

### Results/Performances

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>YES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data management</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Historical test results</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Operating system</td>
<td>Windows</td>
<td>Windows</td>
</tr>
<tr>
<td>Results screen</td>
<td>PC</td>
<td>PC</td>
</tr>
<tr>
<td>Displayed data</td>
<td>Blood glucose, Blood pressure and body temperature</td>
<td>SpO2%, HRV data analysis, photoelectrical Plethysmography analysis and waveform, conductance values, body composition and Blood pressure.</td>
</tr>
<tr>
<td>Data acquisition</td>
<td>Upload from the device memory</td>
<td>upload from backup folder located in the C/Drive of the PC or upload from the device memory</td>
</tr>
<tr>
<td>Data analysis</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>Indication for use</td>
<td>At home and clinical settings</td>
<td>Clinical settings</td>
</tr>
</tbody>
</table>

## 9. Performances and Effectiveness

1. Software verification & validation (D-11SRS/SDS/ D-12 STD/ STR D-33 and 34)
2. Risk management (D-28)
10. General Safety Concerns
The data come from medical devices with 510k clearance:
• Contec 08A software K110774. Applicant: Contec Medical Systems CO. LTD Product code: DXN
• Electro Sensor Oxi (ESO) software K102442. Applicant: LD Technology LLC Product Code DQA
• EIS-GS Software K102166. Applicant: LD Technology LLC Product Code GZO
• ES-BC Software K103026. Applicant: LD Technology LLC Product Code MNW

11. Standards
• Guidance for: Industry; FDA staff; and Content of Premarket Submissions for Software Contained in Medical Devices May 11, 2005
• ISO 14971: Medical devices — Application of risk management to medical devices. March 01 2007
• ISO 62304: Medical device software -- Software life cycle processes. May 1 2006

12. Conclusions
Electro Sensors Complex Software (ES Complex Software) is equivalent in performances, technology, safety and efficacy to the legally marketed predicate devices.

Signature:

Albert MAAREK

Premarket notification [510K] Number: K113264
LD Technology, LLC  
c/o Mr. Albert Maarek  
100 N. Biscayne Blvd, Suite 500  
Miami, FL 33132

Re: K113264  
Trade/Device Name: Electro Sensor Complex Software  
Regulation Number: 21 CFR 870.1130  
Regulation Name: Noninvasive blood pressure measurement system  
Regulatory Class: Class II  
Product Code: DXN, DQA, GZO  
Dated: February 29, 2012  
Received: March 1, 2012

Dear Mr. 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 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,

\[Signature\]

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

Enclosure
Device Name: Electro Sensors Complex Software (ES Complex Software)

Indications for Use:
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Prescription Use X ___ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (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)

M. A. Kilcherman
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113264