MAR – 2 2012

L.D Technology LLC.

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

<div align="center">

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

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

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

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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:
21CFR 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

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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.
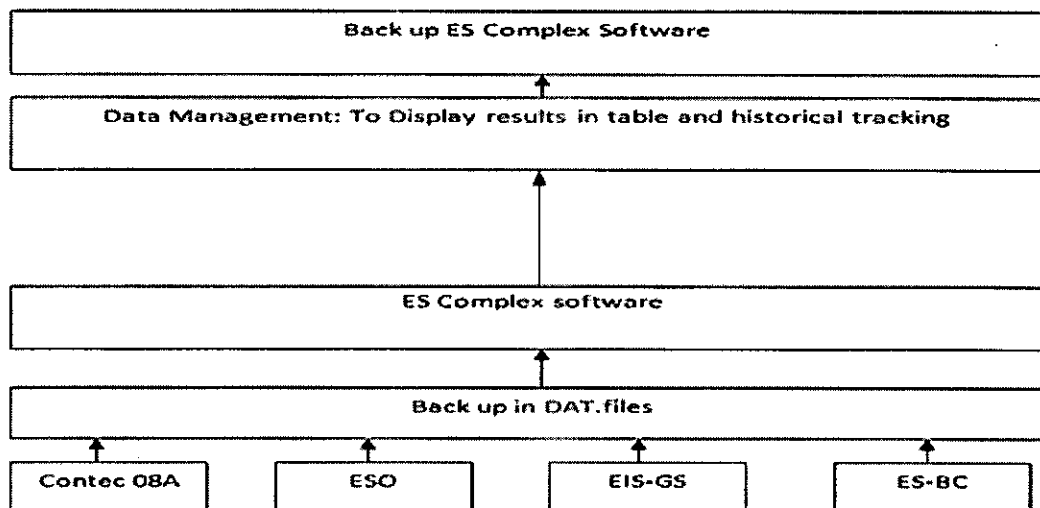The ES Complex software is intended for use in clinical settings as an aid for health care professionals to review, analyze and evaluate the historical tests results.

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 27Mb

Software performances

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┌─────────────────────────────────────────────────────────────┐
│                Back up ES Complex Software                   │
└─────────────────────────────────────────────────────────────┘
                              ▲
┌─────────────────────────────────────────────────────────────┐
│  Data Management: To Display results in table and historical │
│                          tracking                            │
└─────────────────────────────────────────────────────────────┘
                              ▲
┌─────────────────────────────────────────────────────────────┐
│                     ES Complex software                      │
└─────────────────────────────────────────────────────────────┘
                              ▲
┌─────────────────────────────────────────────────────────────┐
│                     Back up in DAT.files                     │
└─────────────────────────────────────────────────────────────┘
      ▲               ▲               ▲               ▲
┌───────────┐   ┌───────────┐   ┌───────────┐   ┌───────────┐
│ Contec 08A│   │    ESO    │   │  EIS-GS   │   │   ES-BC   │
└───────────┘   └───────────┘   └───────────┘   └───────────┘
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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.

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8. Table of comparison

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

Name device (510k number)	Health care system software K110948	ES Complex Software : uploaded data
Intended use	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	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.
Results/Performances		
Data management	YES	YES
Historical test results	YES	YES
Operating system	Windows	Windows
Results screen	PC	PC
Displayed data	Blood glucose ,Blood pressure and body temperature	SpO2%, HRV data analysis, photoelectrical Plethysmography analysis and waveform, conductance values, body composition and Blood pressure.
Data acquisition	Upload from the device memory	upload from backup folder located in the C/Drive of the PC or upload from the device memory
Data analysis	NO	NO
Indication for use	At home and clinical settings	Clinical settings

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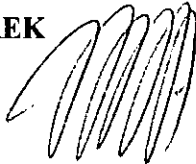
11. Standards
- Guidance for: Industry; FDA staff; and Content of Premarket Submissions for Software Contained in Medical Devices May 11, 2005
- ISO 14971: Medical devices — Application of risk management to medical devices. March 01 2007
- ISO 62304: Medical device software -- Software life cycle processes.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

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

MAR – 2 2012

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,

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

Enclosure

Indications for Use

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

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.

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.H. Hillebrenn

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number___K113264___

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