MAY 2 2 2014

Special 510(k) Summary
ANS 1 Software

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

1. Device Trade Name of the device: **ANS 1 Software**
Device Common name: ANS Data management software
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 Codes: DXN, DQA, GZO and MNW
Classification: Class II
Classification Panel: Cardiology/Neurology

2. Submitter's Identification:
Manufacturer: L.D TECHNOLOGY LLC
CEO of LD Technology: Albert MAAREK
Address:
L.D Technology
100 N.Biscayne Blvd, Suite 502
Miami, FL, 33132, USA
Tel: 305-379-9900
Fax: 305 397 1115
Email: albert.ldteck@gmail.com

3. Predicate legally marketed (unmodified) device
Trade name: ES Complex Software 510K number K113264 Applicant and Manufacturer: LD TECHNOLOGY LLC (Same as new device) Product codes: DXN, QDA, GZO and MNW

3. **Intended use**
ANS1 Software is an optional software accessory for use with the following models with data management capabilities: a) TM-Oxi (Oximeter and blood pressure device) and b) SudoPath (Galvanic Skin response) and c) ES-BC (Body Composition Analyzer).
When used in combination with TM-Oxi and/or SudoPath, and/or ES-BC devices, the ANS1 software uploads the data of the devices, analyzes the data, and then displays the data in a computer for enhanced data management.
The ANS1 software is intended for use in clinical settings as an aid for health care professionals to review, analyze, and evaluate the historical tests results.
The device provides values. It is the physician responsibility to make proper judgment based on these numbers.

The ANS1 software data are stored in back up files located on the PC.
The software is intended for use only with adult subjects.
Prescription Use: Federal law restricts this device to sale by or on the order of a physician.

4. Device Description and Comparison
Devices' comparison Table AN1 / ES Complex

Name device (510k number)	ANS1 Software	ES Complex Software K113264
Intended use	ANS1 Software is an optional software accessory for use with the following models with data management capabilities: a) TM-Oxi (Oximeter and blood pressure device) and b) SudoPath (Galvanic Skin response) and c) ES-BC (Body Composition Analyzer) When used in combination with TM-Oxi and/or SudoPath, and/or ES-BC devices, the ANS1 software uploads the data of the devices, analyzes the data, and then displays the data in a computer for enhanced data management. The ANS1 software is intended for use in clinical settings as an aid for health care professionals to review, analyze, and evaluate the historical tests results.	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 used in combination Contec 08A and ESO, and/or EIS-GS and/or ES-BC, the ES Complex software uploads the data of the devices, analyzes the ESO and Contec08A data and then, 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	SpO2%, HRV analysis, photoelectrical Plethysmography analysis, conductance values body composition and Blood pressure.	SpO2%, HRV analysis, photoelectrical Plethysmography analysis, conductance values body composition and Blood pressure.
Data acquisition	Direct acquisition and/or upload from the device Memory	Direct acquisition and/or upload from the device Memory
Data analysis	YES	YES
Indication for use	clinical settings	Clinical settings

5. Type of device

ANS 1 is a software for data management

6. Software Specifications

- Hardware platform: Laptop or PC based workstation (Intel architecture)

- Operating system: Windows 7/8
- Use of Off-the-Shelf software: Windows 7/8 and PDF
- Language: C++
- Microsoft Visual C++ compiler requirements: 2 GB free space
- Program size requirements 27Mb

7. Comparison with the legally marketed (unmodified) device:
The submission is complying with the Items required under §807.87
Similarities:
The modified device ANS1 Software has the following similarities to ES complex Software which has previously received 510(k) clearance:

- Has the same intended use
- Upload and manage the same data
- Do not affect the Fundamental Scientific Technology
- Do not change the prescription for use

Modifications:
Trade name: Change of the Trade name of the device
Software: Data management come from different cleared devices.
Labeling: Label was modified with the new trade name of the device (ANS1 to replace ES Complex)
Instructions for Use were modified according to the new cleared devices associated with the software.

8. Special 510k requirements
The modified device ANS1 software is complying with the Items required under §807.87 for a special 510k submission.

9. Performances and Effectiveness
1. New risk management
2. Software verification (SRS/SDS/STD/STR)
3. Summary of Design Control Activities and Declaration of Design control conformity

10. General Safety Concerns
The fact to use the data from different cleared devices not affects the general safety concerns

Conclusions
The ANS 1Software is equivalent in performance, technology, safety and efficacy to the legally marketed (unmodified) predicate device ES Complex Software.

Signature:

Albert MAAREK

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -
WO66-G609
Silver Spring, MD 20993-002

May 22, 2014

LD Technology, LLC
c/o Mr. Albert Maarek
President
100 Biscayne Blvd
Suite 502
Miami, FL 33132 US

Re: K140412
Trade/Device Name: ANS1 Software
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN, DQA, GZO
Dated: April 22, 2014
Received: April 25, 2014

Dear Mr. 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.

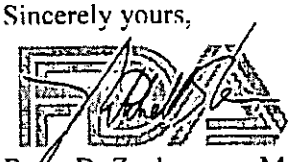
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



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

K140412

Indications for Use

510(k) Number: 140412

Device Name: ANS1 Software Indications for Use:

ANS1 Software is an optional software accessory for use with the following models with data management capabilities: a) TM-Oxi (Oximeter and blood pressure device) and b) SudoPath (Galvanic Skin response) and c) ES-BC (Body Composition Analyzer)

When used in combination with TM-Oxi and/or SudoPath, and/or ES-BC devices, the ANS1 software uploads the data of the devices, analyzes the data, and then displays the data in a computer for enhanced data management.

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The ANS1 software data are stored in back up files located on the PC.

The software is intended for use only with adult subjects.

Prescription Use X _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Date: 2014.05.22 15:05:09 -04'00'