L.D Technology LLC.

MAR 2 9 2011

510(k) Premarket Notification Number: K103026

Preparation date: September, 15 2010

510(k) Summary
E.S-BC Electro Sensor / Body Composition

Name of the device: **Electro Sensor- Body Composition**
Common name: E.S-BC
Impedance Plethysmograph
Regulation number:
21 CFR 870.2770 Product Code: MNW
Classification: Class II
Classification Advisory: Cardiovascular

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 LLC
Owner of LD Technology: MAAREK Albert
Address:
L.D Technology
100 N.Biscayne Blvd, Suite 500
Miami, FL, 33132, USA
Tel: 305-379-9900
Fax: 305-468-3956
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, 15, 2010

2. Device Name / Classification
E.S-BC
Electro Sensor-Body Composition
System components:
21 CFR 870.2770 Product Code: MNW
Classification: Class II
Classification Advisory: Cardiovascular

3. Predicate legally marketed devices
BC body composition software, K070999 Applicant: RJL systems. Inc Product code MNW
DF50 Body Composition Analysis K052395 Applicant: ImpediMed Limited. Product code: MNW

4. Device Description
Description of the features
The E.S- BC is a single frequency electrical bioimpedance analyzer. The device accurately measures current, voltage and phase angle, and calculates impedance, resistance and reactance. These measurements and calculations are used to estimate the body composition: fat-free mass (FFM) and fat mass (FM), total body water (TWB) and fluid distribution: intracellular water, and extracellular water.

It has a tetra-polar set of leads, which are attached to self- adhesive skin electrodes.
The E.S- BC has two operating modes: Direct and Algorithm.
Direct Mode measures and displays values for impedance (Z), phase (Ph), resistance (R) and reactance (Xc).
Algorithm Mode displays estimates of fat-free mass (FFM) ,fat mass (FM), total body Water (TBW), intracellular water (ICW), and extracellular water (ECW), plus their percentages. The device computes these values using accepted peer reviewed published algorithms tailored to the patient type: general population, obese patients, or children.

5. Indications or Intended use
Calculation and Historical Tracking of:

- Actual Resistance
- Actual Reactance
- Actual Impedance
- Actual Phase Angle (PA)
- Estimated Body Fat Mass (FM)
- 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)
- Actual Body Mass Index (BMI)

The device is not intended for use for diagnosis.
The actual resistance, reactance, impedance and phase angle have no clinical utility and are for calculation of body composition only.
The data are stored in PC in the Backup system of the E.S-BC software.

As regard to the estimated TWB , ICW and ECW , the device is intended for use on healthy subjects' over 12 years old and under 80 years old and non-Hispanic whites, non-Hispanic blacks and Mexican Americans in the US population .
As regard to the estimated FM and FFM, the device is intended for use on healthy subjects over 19 years old and under 63 years old and Caucasian and Hispanic Americans in the US population.
The device is for over-the-counter use

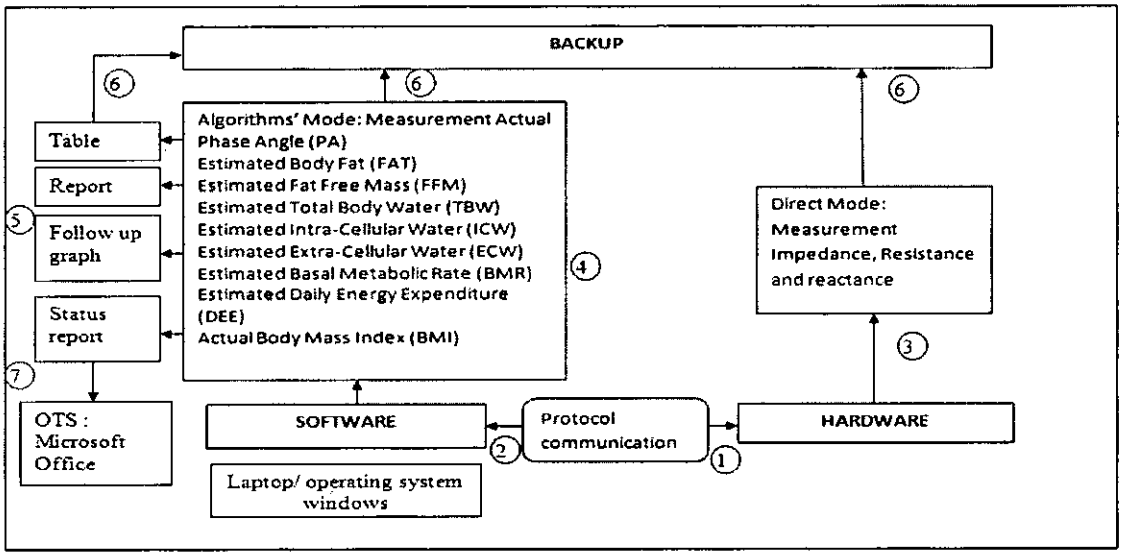
6. Performances, specifications and materials
Technical specifications
Box technical specifications

Power supply	5V (power supply by USB port)
Electrical Classification	Class II
Degree of protection against electric shocks	BF
Operating mode	Continuous use
Current in operating mode	200µ A ± 10 µA
Range Frequency in operating mode	50 KHz ± 100 Hz
Resistance range	0 to 1000 ohms
Impedance resolution	0.1 ohms
Phase resolution	0.1 degree
Galvanic decoupling of the analogical part,	3 KV
Box Dimensions in mm	128 X 143 X 33
Box Weight kg	1,2

Accessories

Component	Technical specifications
4 disposable electrodes	Ref 3M
Connection	Redel 3P
Calibration box	Ref. CPA 5509
Reusable Cable	Ref : OEM459-C
USB cable	Ref: USB 2.0

Features' chart flow



Comments of the chart flow

1. Protocol communication1: The hardware is USB port of the laptop powered and the hardware functions are controlled by the software :
    - Start /pause
    - Time of measurement
    - Testing and calibration
2. Protocol communication 2: Hardware data transmission to the software
3. Hardware measurement (direct mode)
4. Software analysis : algorithms application to the hardware measurement (algorithms 'mode)
5. Results in table, report, follow up graphs and status report.
6. Backup of the direct mode and algorithms 'mode results
7. Off-the-Shelf software interface to edit and print the status report (Microsoft Office Word).

Other specifications

- Programming language: C++
- Hardware platform : PC based workstation (Intel architecture)
- Operating system : Windows
- Use of Off-the-Shelf software : Microsoft office Word 2003 or 2007

7. Contra-indications

- Patients undergoing external defibrillation
  Risk: The injected voltage and current could provoke injury to the patient.
- This device should not be used in association with or presence of defibrillators, cardiac pacemakers, patients connected to electronic life support devices, or any implanted electronic device.
  Risk: The injected voltage and current could provoke injury to the patient.

⚠ **8. Undesirable side effects:**
Side effects or adverse reactions are none known to date.

9. Substantial equivalence
Predicate legally marketed devices
BC body composition software, K070999 Applicant: RJL systems. Inc Product code MNW
DF50 Body Composition Analysis K052395 Applicant: ImpediMed Limited. Product code: MNW

Similarities:
Substantial equivalence

- ✓ Same intended use

Differences:

- ✓ The device is USB interface powered
- ✓ The hardware data's are directly transmitted to the software via the USB port of the laptop.
- ✓ Some peer reviews 'algorithms chosen are different

I.e. Tables of comparison of the E.S-BC modules and SE discussion: i.e. Executive summary

11. Performances and Effectiveness

Performance testing:

1. Testing and Calibration
2. Software verification (SRS/STD/STR)
3. Clinical investigation (Miami University)

The facts that:

- ✓ The device is USB interface powered
- ✓ The hardware data's are directly transmitted to the software via the USB port of the laptop.
- ✓ Some peer reviews 'algorithms chosen are different

Do not affect the performances and the effectiveness of the E.S/BC system as shown by the testing and calibration and the clinical investigation conclusion.

12. General Safety Concerns
The facts that:

- ✓ The device is USB powered
- ✓ The hardware data's are directly transmitted to the software via the USB port of the PC.

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

13. Standards

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

Conclusions

E.S-BC is equivalent in performances, technology, safety and efficacy to the legally marketed predicate devices

Signature:

Albert MAAREK

Premarket notification [510K] Number: K103026

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

L.D. Technology, LLC
c/o Richard Clement, M.D.
11459 NW 34 Street
MIAMI FL 33178

MAR 29 2011

Re: K103026
Trade/Device Name: E.S-BC (Electro Sensor-Body Composition)
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: March 22, 2011
Received: March 25, 2011

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. 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,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103026

Device Name: _E.S-BC (Electro Sensor-Body Composition)

Indications for Use:
Calculation and Historical Tracking of:

- Actual Resistance
- Actual Reactance
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The device is for over-the-counter use

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X _____ (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 Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K103026