L.D Technology LLC.

510(k) Premarket Notification Number: K102166
Preparation date: June 29, 2010

DEC 10 2010

510(k) Summary
EIS-GS (Electro Interstitial Scan-Galvanic Skin)

Name of the device: **Electro Interstitial Scan-Galvanic Skin**
Common name: EIS-GS
Regulation number: 21 CFR 882.1540
Product Code: GZO
Classification: Class II
Classification Advisory: Neurology

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
E **mail:** albert.ldteck@gmail.com

Contact Information:
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: June 29, 2010

2. Device Name/Classification
EIS-GS (Electro Interstitial Scan-GS)
System components:
21 CFR 882.1540
Product Code: GZO
Classification: Class II
Classification Advisory: Neurology

3. Predicate legally marketed device
SUDOSCAN 510(k) Number 100223: Manufacturer - Impeto Medical, 17 rue Campagne Premiere, 75014 PARIS, France.

4. Device Description

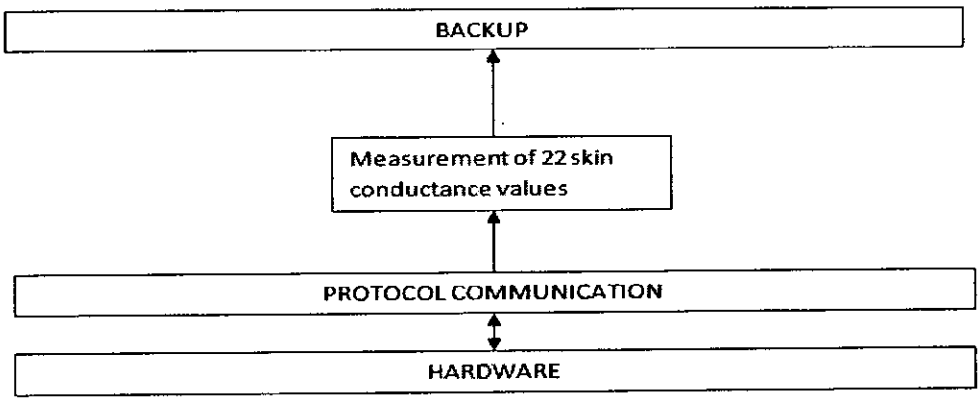
The EIS-GS system is a programmable electro medical system including:

- USB plug and play hardware device including an electronic box , 6 disposable electrodes, reusable electrodes and reusable cables
- Software installed on a computer.

Protocol communication: USB port.
Through the 6 tactile electrodes, a weak current with a very low frequency is sending alternatively between 2 electrodes with a sequence and the EIS-GS system is recording the electrical conductivity of 22 pathways of the human body.
In accordance with the 21 CFR 882.1540, the EIS-GS system is a galvanic Skin response device that provides skin conductance measurements on the PC screen.

EIS-GS system features
Hardware feature:
To Record the intensity changes of 22 body parts/pathways following the sending of a weak current and an imposed weak tension (1.28V) with a very low frequency.
The data are transmitted via the USB port from the hardware to the PC (software).

Software chart flow



5. Intended use and indications for use

EIS-GS (Electro Interstitial Scan-GS) is a medical device for the measurement of galvanic skin response.

The device is not intended for use in any diagnosis.
The data are stored in PC in the Backup system of the EIS-GS software.
The device is intended for use on healthy adult subjects.
The device is intended use in practitioner's office and clinical setting.

Prescription Use Caution: Federal law restricts this device to sale by or on the order of a physician

6. Performances, specifications and materials

Technical specifications

Hardware technical specifications:

Power supply	USB interface
Current in operating mode	1.28 V Frequency 700 Hz and 12 µA
Power consumption	200mA
Classification	Class II
Degree of protection against electric shocks	BF
Operating mode	Continuous use
Galvanic decoupling of the analogical part,	TRACO DC/DC 4 KV
Dimensions in mm	128 X 143 X 33
Weight kg	1,2

Accessories

Component	Technical specifications
Disposable forehead electrodes Ref 3M dot	Ag/AgCl 1.575 cm^2
Reusable hand plates Ref CPA 3504 –AR CPA 3504 –AL	Polished stainless steel grade AISI 304 Size:272 cm^2
Reusable feet plates Ref. CPA 3504-F	Polished stainless steel grade AISI 304 Size :330 cm^2
Audio-type cables to connect electrodes/ plates to the box Ref. PG395/15RN	1.5m long armored insulated cables. Color-coded for ease of use. Red one on the left Black one on the right
Calibration Box Ref.CPA 5509	Box including Different resistors 80 and 100 KOhms
USB cable. Ref. USB cable	2 m long USB 2.0

7. Contraindications

- Dermatological lesions in contact with the electrodes or excessive perspiration.
  Risk: The conductivity values will be changed and the results not accurate.
- 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.
- People unable to be held seated.

Risk: The calibration of the device was performed the patient in sitting position, and therefore in other position, the conductivity values will be changed and the results not accurate.

- Metal pins or prostheses on the level of the extremities or the joints.
  Risk: the conductivity values will be changed and the results not accurate
- This device should not be used on pregnant women.
  Risk: The effects on the fetus, as well as accuracy of readings are unknown.
- An absence of one or more limbs.
  Risk: The conductivity values will be changed and the results not accurate
- Do not use the system in the following conditions :
  - ✓ The Floor in synthetic material.
    Risk: The floor in synthetic material will increase the Electrostatic discharge and the device could short and in this case a message will appear and the measurement will stop (i.e. troubleshooting).
  - ✓ Relative humidity < 30%.
    Risk: The low humidity will increase the Electrostatic discharge and the device could short and in this case a message will appear and the measurement will stop (i.e. troubleshooting).
  - ✓ Presence of MRI or MR or CT scan.
    Risk: The Electromagnetic environment could short the device and in this case a message will appear and the measurement will stop (i.e. troubleshooting).

Disclaimers

The device is not intended to be use to diagnose any disease or condition since it is intended for use in generally healthy subjects only.

8. Undesirable side effects:

- ✓ Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium.
- ✓ The device should be used only with the leads and electrodes recommended for use by the manufacturer.

9. Substantial equivalence

Predicate legally marketed device

SUDOSCAN 510(k) number 100223: Manufacturer Impeto Medical 17 rue Campagne Premiere, 75014 PARIS, France.

Similarities

- ✓ Same intended use and same technology

New characteristics:

- ✓ Small change as shown in the device comparison table below

Devices' Comparison Table

Table comparison for EIS-GS/SUDOSCAN K100223

Specifications	EIS-GS	SUDOSCAN K 100223
Intended use	Measurement of the galvanic skin response	Measurement of the galvanic skin response
Power supply	5V (power supplied by USB port and computer connected to the 120 V power supply)	5V (power supplied by USB port and computer connected to the 120 V power supply)
Skin conductance measurement	1 to 120 micro Siemens	10 to 100 micro Siemens
Data acquisition duration	120s	120s
Electrical output to the skin	1.28 V	4 V maximum
Electrical output unit duration	1 s	1 s
Power density at electrode	< 0.01 UA/mm2	< 0.01 UA/mm2
Electrical Classification	Class II	Class II
Degree of protection against electric shocks	BF	BF
Sequence of the measurement	Managed by the software	Managed by the software
Display	PC screen .Operating system window 7	PC touch screen. Operating system window XP
Electrodes specifications	3 pairs of electrodes from 15- 330 cm2	3 pairs of electrodes from 7-300 cm2
Accessories	cable and Reusable electrodes (Large Plates and disposable electrodes)	cable and Reusable electrodes (Large Plates and disposable electrodes)
Output	USB interface	USB interface / Bluetooth
Electrical isolation between the patient and the AC mains energy.	galvanic isolation between the Analog part and digital part : Optocouplers AC/AC converter	galvanic isolation between the Analog part and digital part : Optocouplers AC/AC converter

Other specifications	EIS-GS	SUDOSCAN K 100223
Anatomic site	Tactile electrodes	Tactile electrodes
Where used	Practitioner	Practitioner
Cleaning and disinfection	Ethyl or isopropyl alcohol (70-90%)	Ethyl or isopropyl alcohol (70-90%)
Standards met	IEC 60601-1 -1 IEC 60601-1-2	IEC 60601-1-1 IEC60601-1-2

11. Performance and Effectiveness

EIS-GS

1. Calibration tests (simulator)
2. Software verification (SRS/SDS/STD/STR).

12. General Safety Concerns

The small changes in the characteristics do not change the general safety to the legally marketed predicate device as shown in the laboratory tests reports. (IEC 60601-1-2 and IEC 60601-1-1.

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

14. Non-clinical Testing

EIS-GS device has been thoroughly tested through verification of specifications and validation, including software validation. Electrical safety and electromagnetic compatibility testing in compliance with IEC 60601 -1-1, IEC 60601-1-2 were also completed.

Conclusion

EIS-GS is equivalent in performance, technology, safety and efficacy to the legally marketed predicate device.

Signature:

Albert MAAREK

Premarket notification [510K] Number: K102166

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

L.D. Technology, LLC
c/o Richard Clement, MD
11459 NW 34 Street
Miami, Florida 33178

DEC 10 2010

Re: K102166
Trade/Device Name: Electro Interstitial Scan – Galvanic Skin (EIS-GS)
Regulation Number: 21 CFR 882.1540
Regulation Name: Galvanic Skin Response Measurement Device
Regulatory Class: Class II
Product Code: GZO
Dated: November 24, 2010
Received: December 1, 2010

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,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

DEC 10 2010

510(k) Number: K102166

Device Name: EIS-GS (Electro Interstitial Scan-Galvanic Skin)

EIS-GS (Electro Interstitial Scan-GS) is a medical device for the measurement of galvanic skin response.

The device is not intended to be used for any diagnosis.
The data are stored in the PC in the backup system of the EIS-GS software.
The device is intended for use only in healthy adult subjects.
The device is intended for use only in practitioner's office and clinical setting.

Prescription Use Caution: Federal law restricts this device to sale by or on the order of a physician.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K102166