



Food and Drug Administration  
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Silver Spring, MD 20993-0002

September 24, 2015

LD Technology LLC  
Albert Maarek  
CEO  
100 N. Biscayne Blvd, Suite 502  
Miami, Florida 33132

Re: K152216  
Trade/Device Name: SudoC  
Regulation Number: 21 CFR 882.1540  
Regulation Name: Galvanic Skin Response Measurement Device  
Regulatory Class: Class II  
Product Code: GZO  
Dated: July 28, 2015  
Received: August 7, 2015

Dear 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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

**Michael J. Hoffmann -S**

for Carlos L. Peña, PhD, MS  
Director  
Division of Neurological  
and Physical Medicine Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K152216

Device Name

SudoC

Indications for Use (Describe)

SudoC device is a medical device for the measurement of galvanic skin response related to the function of the sweat glands.

The SudoC provides values. It is the physician's responsibility to make proper judgments based on these numbers. The device is indicated for use in general adult population.

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

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**L.D Technology LLC.**



510(k) Premarket Notification Number:  
Special 510k number k152216  
Preparation date: July 28, 2015

**Special 510(k) Summary  
SudoC**

**This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.87**

1. Device Trade Name of the device: **SudoC**  
Device Common name: Galvanic Skin  
Response Regulation number:  
21 CFR 882.1540 Product Code: GZO  
Classification: Class II  
Classification Advisory: Neurology

**2. Submitter's Identification:**  
**Manufacturer:** L.D TECHNOLOGY LLC  
CEO of LD Technology: Albert MAAREK  
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Miami, FL, 33132, USA  
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**3. Predicate legally marketed (unmodified) device**  
Trade name: SudoPath, Common name: Galvanic skin response 510K number K131568 Applicant and Manufacturer: LD TECHNOLOGY LLC (Same as new device) Product code GZO.

**4. Intended use**  
SudoC is a Galvanic skin response measurement device related to the function of the sweat glands.  
The SudoC provides values. It is the physician's responsibility to make proper judgments based on these numbers.  
The device is indicated for use in general adult population

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

**5. Device Description and Comparison**  
**Devices' comparison Table modified SudoPath / unmodified SudoPath**

Specifications	SudoC	SudoPath k 131568
Intended use	Galvanic Skin Response measurement device related to the function of the sweat glands	Galvanic Skin Response device measurement
Prescription for use	Physician	Physician
Hardware	Same Hardware with exactly the same specification	SudoPath Hardware
Material used in contact with the patient	Conductive disposable cloth electrode	Stainless steel
Fundamental Scientific Technology	Sympathetic skin potential response and sweat glands	Sympathetic skin potential response and sweat glands
Number of electrodes in contact with the patient	4	4
Sequence of measurement	Software control and sequence between feet.	Software control and sequence between feet and hands
Time of measurement for each pathway	Software control , each pathway is measured during 30 seconds	Software control , each pathway is measured during 30 seconds
Cleaning and disinfection	Ethyl or isopropyl alcohol (70-90%) for lead wires and cables. Electrodes are single use.	Ethyl or isopropyl alcohol (70-90%) for electrodes, lead wires and cables
Standards met	IEC 60601-1 -1 IEC 60601-1-2	IEC 60601-1-1 IEC60601-1-2
Range of conductance measurements	1 to 120 micro Siemens	1 to 120 micro Siemens
Data acquisition duration	120s	120s
electrical output to skin	1.28V	1.28V
active surface area of electrode	44 cm <sup>2</sup> for each disposable electrode placed on the feet	272 cm <sup>2</sup> for the hand plates 330 cm <sup>2</sup> for the foot plates
current density at electrodes	< 0.01 UA/mm <sup>2</sup>	< 0.01 UA/mm <sup>2</sup>

### Type of device

The SudoC is a programmable electro medical system including:

- USB plug and play hardware device including an electronic box, 2 reusable cables to connect the box to electrodes and 2 tactile electrodes placed on the sole of each foot.
- Software installed on a computer.

As a galvanic skin response measurement device, it measures the skin resistance (i.e., conductance).

### Comparison with the legally marketed (unmodified) device:

The submission is complying with the Items required under §807.87

Similarities:

The SudoC has the following similarities to unmodified SudoPath which has previously received 510(k) clearance:

- has the same intended use,
- uses the same Hardware and not affect the hardware manufacture process
- does not affect the Fundamental Scientific Technology
- does not change the prescription use

Modifications:

Accessories: The hand electrodes are no longer used and the stainless steel foot electrodes has been replace by a conductive disposable cloth electrodes.

Software: New design and change in time and sequence of measurement.

Indication for use were updated the addition of the phrase “related to the function of the sweat glands” which does not constitute a new intended use. It clarifies the utility of the device.

Labeling: Instructions for Use were modified according to the changes.

## **6. Performances and Effectiveness**

The modifications perform to the proposed device do not change the performance of the device has shown with:

1. New risk management
2. Software verification (SRS/SDS/STD/STR)
3. Summary of Design Control Activities and Declaration of Design control conformity.
4. Comparison of the conductance values using stainless steel electrodes versus conductive disposable cloth electrode.
5. The removal of the hand electrodes does not affect the performance of the device since the galvanic skin response measurement is performed in the area with the higher density of sweat glands (sole of the feet).

## **7. General Safety Concerns**

The electrical and EMC risk are not affected since the new device using the same hardware

The removal of the hands electrodes cannot affect the device safety.

The new material used for the foot electrodes is 510k cleared.

## **8. Conclusions**

The SudoC device is equivalent in performances, technology, safety and efficacy to the legally marketed (unmodified) predicate device

**Signature:**

**Albert MAAREK**



**Premarket notification [510K]**

**Number: K152216**