K131568

L.D Technology LLC.

510(k) Premarket Notification Number:
Special 510k
Preparation date: February 16, 2013

JUN 2 8 2013

Special 510(k) Summary
SudoPath

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: **SudoPath**
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
Address:
L.D Technology
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3. Predicate legally marketed (unmodified) device
Trade name: EIS-GS, Common name: Galvanic skin response 510K number K102166 Applicant and Manufacturer: LD TECHNOLOGY LLC (Same as new device SudoPath) Product code GZO.

4. **Intended use**
SudoPath is a Galvanic skin response measurement device.
The SudoPath 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 SudoPath / EIS –GS

Specifications	SudoPath	EIS-GS k 102166
Intended use	Galvanic Skin Response device	Galvanic Skin Response device
Prescription for use	Physician	Physician
Hardware	Same Hardware with exactly the same specification	EIS-GS Hardware
Material used in contact with the patient	Stainless steel	Stainless steel AgAgCl disposable electrodes
Fundamental Scientific Technology	Sympathetic skin response and sweat glands	Sympathetic skin response and sweat glands
Number of electrodes in contact with the patient	4	6
Number of conductance values	4	22
Sequence of measurement	Software control and simplified sequence between feet and hands	Software control , all the possibilities of measurements between the 6 tactile electrodes
Time of measurement for each pathway	Software control , each pathway is measured during 30 seconds and 4 times (2 pathways 2 times)	Software control , each pathway is measured during 1 seconds and 88 times (22 pathways 4 times)
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
Range of conductance measurements	1 to 120 micro Siemens	1 to 120 micro Siemens
Data acquisition duration	120s	128s
electrical output to skin	1.28V	1.28V
active surface area of electrode	272 cm2 for the hand plates 330 cm2 for the foot plates	15.75 cm2 for forehead electrodes 272 cm2 for the hand plates 330 cm2 for the foot plates
current density at electrodes	< 0.01 UA/mm2	< 0.01 UA/mm2

Type of device

SudoPath 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 4 tactile electrodes placed on the sole of the feet and on the palm of the hands.
- 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 modified device SudoPath has the following similarities to EIS-GS which has previously received 510(k) clearance:

- has the same intended use,
- uses the same Hardware and not affect the hardware manufacture process
- Has the same material in used accessories
- Do not affect the Fundamental Scientific Technology
- Do not change the prescription use

Modifications:

Trade name: Change of the Trade name of the device

Accessories: The 2 frontal disposable electrodes are no longer used

Software: New design and change in time and sequence of measurement and therefore in displayed results of conductance value (Only 4 values and not 22)

Indication for use were updated to match with the cleared devices with the same intended use

Labeling :Label on the box was modified with the new trade name of the device (SudoPath Replace EIS-GS)

Instructions for Use were modified according to the new design of the software and new process of measurement and displayed results of conductance values .

6. Substantial Equivalence

The modified device SudoPath is complying with the Items required under §807.87 for a special 510k submission.

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

12. General Safety Concerns

The new device uses the same Hardware and not affects the hardware manufacture process and has the same material in used accessories

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

Signature:

Albert MAAREK

Premarket notification [510K] Number: K131568

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

June 28, 2013

LD Technology LLC
c/o Mr. Albert Maarek
100 N. Biscayne Blvd, Ste 500
Miami, FL 33132

Re: K131568
Trade/Device Name: SudoPath
Regulation Number: 21 CFR 882.1540
Regulation Name: Galvanic Skin Response Measurement Device
Regulatory Class: Class II
Product Code: GZO
Dated: May 28, 2013
Received: May 30, 2013

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 contact 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. 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 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,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting 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): **K131568**

Device Name: **SudoPath**

Indications For Use:

SudoPath device is a medical device for the measurement of galvanic skin response.

The SudoPath 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.

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)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

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