impetomedical

510(k) Summary

K100233

1. Contact Details

Applicant Name: IMPETO MEDICAL

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JUN 14 2010

Name of contact person:
Kye Cheung
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Date Prepared: June 11, 2010

2. Device Name

Trade Name: SUDOSCAN

Common Name: SUDOSCAN

Classification Name: Galvanic Skin Response Measurement Device

Device Class: Class II

Device Code: GZO

Classification: 882.1540

3. Legally Marketed Predicate Device(s)

The Impeto Medical SUDOSCAN device is substantially equivalent to the EDX Epi-Scan device cleared under 510(k) K032935.

510(k) Number	Product Code	Trade Name	Manufacturer
K032935	GZO	EDX Epi-Scan	EDX Epi-Scan 130 Main Road Huntsville, AL

4. Device Description

SUDOSCAN device is based on two well-known principles, reverse iontophoresis and electrochemistry. SUDOSCAN device collects physiological data by means of chrono-amperometry and processes them with analysis software. SUDOSCAN device uses both technologies, coupled and complemented with exclusive software which analyzes cutaneous conductance data collected through the chronoamperometric measurements.

SUDOSCAN device is composed of:

- → The analog acquisition electronic circuitry with low-noise front end
- → The multiplexing control unit for selecting the appropriate acquisition channels
- → The signal formatting and processing capabilities
- → The optically isolated USB interface controller
- → The power converter,
- → The connection circuitry to 6 electrodes placed on the feet, the hands and the forehead of the patient, is integrated into a customized touch-screen Windows XP-based Industrial-grade personal computer running the proprietary SUDOSCAN acquisition control and analysis software also responsible for archiving measurements taken on all patients.

5. Intended Use/Indications for use

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

6. Substantial Equivalence Comparison

A comparison of the characteristics of the SUDOSCAN and the Epi-Scan predicate device is provided above.

Characteristics	SUDOSCAN	Predicate Device EDX Epi-Scan
Indications for use	Measurement of galvanic skin response	Measurement of galvanic skin response
Presentation	Desktop device	Handheld device
Measurement range (Skin conductance range)	10-100,000 nS/cm²	1 - 80,000 nS/ cm^2

Characteristics	SUDOSCAN	Predicate Device EDX Epi-Scan
Measurement lower (Skin conductance resolution)	1nS/cm^2	1nS/cm^2
Acquisition duration total	120s	54 time 3s=162s (6 locations with 9 points of measurement each)
Electrical output to the skin	4V max	3V max
Electrical output frequency	Continuous	Continuous
Electrical output unit duration	1s	3s
Power Density (at electrode)	0,01 uA/mm^2	0.03 uA/mm^2
User Display	VGA Color LCD 1024*768	Liquid Crystal
User control	Touch screen	6 push button switches (keys)
Audible Indicators	Integral Speaker Optional Headphone	Integral Speaker Optional Headphone
Interface	USB (Internal)	USB (cable supplied)
Power source	5V provided by USB	2 disposable (non rechargeable) AA batteries
Electrodes surface area (*)	7 to 300 cm^2	1 to 3 cm^2
Standards met	IEC60601-1-1, EN60601-1-2 Medical Device Directive 93/42/EEC	IEC60601-1-1, EN60601-1-2 Medical Device Directive 93/42/EEC
Test report	Subject details (patient data). Indication for referral, entered by examining physician. Method. Result. Impressions entered by examining physician. The measured STC values of the test. Three average value of 18 STC measurements.	Subject details (patient data). Indication for referral, entered by examining physician. Method. Result. Impressions entered by examining physician. The measured STC values of the test. One average value of 36 STC measurements.

(*) SUDOSCAN device, with its larger pre-configured electrodes, has simplified Galvanic Skin Response reading by collecting average information primarily on hands, feet and forehead. Both SUDOSCAN and the predicate device measure the Galvanic Skin Response. SUDOSCAN device is able to obtain measurements from a larger area at one time whereas EDX Epi-Scan obtains the measurements by taking several measurements over a period of time and then averaging the data.

7. Non-clinical Testing

SUDOSCAN 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, IEC 60601-1-2 were also completed.

8. Conclusions

Conclusions drawn from SUDOSCAN device testing demonstrate that SUDOSCAN is as safe and effective to perform measurement of Galvanic Skin Response as the legally marketed predicate device EDX Epi-scan and is substantially equivalent.

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

Impeto Medical
c/o Mr. Kye Cheung
4479 Shorepointe Way
San Diego, CA 92130

JUN 14 2010

Re: K100233
Trade/Device Name: Impeto Medical SudoScan
Regulation Number: 21 CFR 882.1540
Regulation Name: Galvanic skin response measurement device
Regulatory Class: Class II
Product Code: GZO
Dated: June 4, 2010
Received: June 4, 2010

Dear Mr. Cheung:

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

510(k) Number: To Be Assigned By FDA K100233

Device Name: Impeto Medical SudoScan

Indications for Use:

The SudoScan system is a medical device for the measurement of galvanic skin responses.

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

PETER G. COMO

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

510(k) Number K100233