DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 21, 2014

IMPETO Medical
c/o Calley Herzog
Biologics Consulting Group, Inc.
400 N Washington Street
Suite 100, Medical Devices Division
Alexandria, VA 22314

Re: K141872
Trade/Device Name: SUDOSCAN
Regulation Number: 21 CFR 882.1540
Regulation Name: Galvanic Skin Response Measurement Device
Regulatory Class: Class II
Product Code: GZO
Dated: October 21, 2014
Received: October 23, 2014

Dear Ms. Herzog:

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" (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 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,

Felipe Aguel -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141872

Device Name
SUDOSCAN

Indications for Use *(Describe)*
The SUDOSCAN System is a medical device for the measurement of galvanic skin response to aid in the assessment of sudomotor function.

SUDOSCAN is indicated for use in the general adult population.

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.

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5. 510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the SUDOSCAN is provided below.

Device Common Name: Galvanic Skin Response Measurement Device

Device Proprietary Name: SUDOSCAN

Submitter:
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Classification Regulation: 21 CFR 882.1540, Class II

Panel: Neurology

Product Code: GZO

Date Prepared: July 7, 2014

Predicate Device: K100233, SUDOSCAN, IMPETO Medical

Indication for Use:

The SUDOSCAN system is a medical device for the measurement of galvanic skin response to aid in the assessment of sudomotor function.

SUDOSCAN is indicated for use in the general adult population.

Device Description:

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

The SUDOSCAN system is composed of:

- analog acquisition electronic circuitry with low-noise front end
- multiplexing control unit for selecting the appropriate acquisition channels
- optically isolated USB interface controller

- power converter
- 4 electrodes placed on the feet and the hands
- touch-screen computer running the proprietary SUDOSCAN software

Performance Data:

The modifications that are the subject of this 510(k) are to the indication statement, labeling and minor software and hardware upgrades. Therefore the performance testing provided in K100233 is applicable to this 510(k). Since its clearance in K100233, the SUDOSCAN was additionally tested for compliance with the following standards:

- IEC 60601-1:2005 + CORR. 1 (2006) + CORR. 2 (2007) Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2: 2007 (Third Edition) Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility
- ANSI/AAMI PC69:2007 Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators.

Substantial Equivalence:

The indication for use for the predicate device (K100233) is similar to that of the subject device. There are two differences, first is the addition of the phrase "to aid in the assessment of sudomotor function" which does not constitute a new intended use. It clarifies the utility of the device. Second is the addition of the phrase "indicated for use in the general adult population". This also does not constitute a new intended use, but clarifies to intended user population.

The technological characteristics of the subject device are identical to that of the predicate. The only difference is that the head electrodes are no longer used or provided and there have been minor upgrades to the device software and hardware. The technological characteristics are substantially equivalent to the predicate device as shown in Table 1.

Table 1: Device Comparison Table

	Proposed Device	**Predicate Device**
Device Name	SUDOSCAN	SUDOSCAN
Manufacturer	IMPETO Medical	IMPETO Medical
510(k) Number	TBD	K100233
Classification Regulation	882.1540, Class II	882.1540, Class II
Product Code	GZO	GZO

	Proposed Device	**Predicate Device**
Indication	The SUDOSCAN system is a medical device for the measurement of galvanic skin response to aid in the assessment of sudomotor function. SUDOSCAN is indicated for use in the general adult population.	The SUDOSCAN system is a medical device for the measurement of galvanic skin responses.
Operating Characteristics	1. Measures difference in skin conductance. 2. Used to provide feedback to physicians, not to diagnose. 3. Skin Contact Pads measure skin conductance.	1. Measures difference in skin conductance. 2. Used to provide feedback to physicians, not to diagnose. 3. Skin Contact Pads measure skin conductance.
Electrode Placement	Hands, Feet	Hands, Feet, Forehead
Skin Conductance Measurement Range	10-100,000 nS/cm^2	10-100,000 nS/cm^2
Skin Conductance Resolution	1 nS/cm^2	1 nS/cm^2
Acquisition Duration (total)	120 seconds	120 seconds
Electrical Output to the skin	4 V max	4 V max
Electrical Output Frequency	Continuous	Continuous
Electrical Output Unit Duration	1 second	1 second
Power Density (at electrode)	0.01 $\mu A/mm^2$	0.01 $\mu A/mm^2$
User Display	VGA Color LCD 1024*768	VGA Color LCD 1024*768
User Control	Touch screen	Touch screen
Audible Indicators	Internal Speaker and Optional Headphone	Internal Speaker and Optional Headphone
Interface	(USB) Internal	(USB) Internal
Power Source	5 V provided by USB	5 V provided by USB
Electrode Surface Area	Hand: 212 cm^2	Hand: 212 cm^2
	Foot: 269 cm^2	Foot: 269 cm^2
	Head: N/A	Head: 7 cm^2

	Proposed Device	**Predicate Device**
Electrode Patient Contact Material	Hand and Feet Electrodes: Stainless Steel (AISI 304)	Hand and Feet Electrodes: Stainless Steel (AISI 304) Head Electrode: Nickel Silver Alloy
Standards Met	IEC60601 -1 -1, EN60601-1-2, ANSI/AAMI PC69	IEC60601 -1 -1, EN60601-1-2
Test Report	- Subject details (patient data) - Indication for referral - entered by examining physician - Method - Result - Impressions – entered by examining physician - Measured STC values of the test - Two average values of 12 STC* measurements: - Hand: Average value of 6 STC measurements - Foot: Average value of 6 STC measurements	- Subject details (patient data) - Indication for referral - entered by examining physician - Method - Result - Impressions – entered by examining physician - Measured STC values of the test - Three average values of 18 STC measurements: - Hand: Average value of 6 STC measurements - Foot: Average value of 6 STC measurements - Head: Average value of 6 STC measurements

*STC: Standard Conductances; the terminology used to describe the ionic current measured by the SUDOSCAN device electrodes.

Substantial Equivalence Conclusion

Based on intended use and technological characteristics, the SUDOSCAN can be found substantially equivalent to the submitter's own predicate device, the SUDOSCAN as cleared in K100233.