



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

October 19, 2015

Medeia, Inc.
% Daniel Lehtonen
Regulatory Consultant
Compliance and Regulatory Services LLC
3771 Southbrook Drive
Dayton, Ohio 45430

Re: K150804
Trade/Device Name: QBioScan
Regulation Number: 21 CFR 882.1540
Regulation Name: Galvanic skin response measurement device
Regulatory Class: Class II
Product Code: GZO
Dated: September 14, 2015
Received: September 16, 2015

Dear Mr. Lehtonen:

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)

K150804

Device Name

QBioScan

Indications for Use (Describe)

QBioScan is indicated for the measurement of galvanic skin response to aid in the assessment of the sudomotor function.

The device is intended for use on the general adult population in medical clinics, healthcare practices and out-patient departments of hospitals.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the Requirements of Safe Medical Device systems Act 1990 and 21 CFR Sec. 807.92

510(k) Number: K150804

a1 APPLICANT INFORMATION:

Date Prepared: March 16, 2015

Name: Medeia, Inc.
Address: 80 S.W. 8th St.
Suite 2000
Miami, FL 33130

Contact Person: Slav Danev
Phone Number: +1 800 433 4609
Fax Number: +1 800 433 4609
Email: danev@medeia-inc.com

a2 NAME OF DEVICE:

Trade Name: QBioScan™, model HW4
Common Name: Galvanic Skin Measurement Device
Classification Name: Galvanic Skin Measurement Device (21 CFR 882.1540 / GZO)

a3 PREDICATE DEVICE:

Device Name: Sudoscan
K Numbers: K100233 and K141872
Manufacturer: Impeto Medical
17, rue Campagne Première
75014 Paris - France

The FDA database for recalls was searched during the writing of this 510(k) submission and no recalls for the predicate device or manufacturer were found.

a4 DESCRIPTION OF THE DEVICE:

QBioScan™ is a galvanic skin response measurement device intended for the collection and display of galvanic skin response recorded by the device. The device consists of the following components:

- an off-the-shelf computer with proprietary device software pre-installed
- a custom electronics box that houses the QBioScan circuitry
- a USB cable to connect the electronics box to the computer
- reusable electrode lead cables
- reusable hand and foot electrodes and optional disposable forehead electrodes
- an off-the-shelf printer (optional)

The device allows for a evaluation of sweat gland function based on a measuring method where patients are in contact with surface electrodes (reusable stainless-steel plates and optional disposable electrodes) and are exposed to an incremental low voltage (under the 60601-1 standard safety limits). The device tests the electrochemical reaction between electrodes and the chloride ion released by the stimulated sweat glands. This active test method provides information and evidence of a sweat gland dysfunction that might otherwise not be detectable in a physiological examination. The Bioelectrical Conductance (BEC, in micro-Siemens, μS) representing galvanic skin response for the hands and feet are expressed as quantitative results

along with an asymmetry value expressed as the percent difference between the BEC values of the right / left hands and the right / left feet.

The device does not provide any direct diagnosis rather the device provides information to the physician for inclusion in their decision making process.

a5 STATEMENT OF INTENDED USE:

QBioScan is indicated for the measurement of galvanic skin response to aid in the assessment of the sudomotor function.

The device is intended for use on the general adult population in medical clinics, healthcare practices and out-patient departments of hospitals.

a6 TECHNOLOGICAL CHARACTERISTIC COMPARISON:

Determination of the bioelectrical conductance value of the hands and feet via application of a variable amplitude low voltage, low current excitation is the technological principle of both the subject and predicate devices. The following table shows the similarities and differences between the devices. The differences have no material impact on the equivalence between the devices.

	Proposed Device	Predicate Device	Predicate Device
510(k) Number	N/A	K100233	K141872
Device Name	QBioScan™	SUDOSCAN	SUDOSCAN
Manufacturer	Medeia, Inc.	IMPETO Medical	IMPETO Medical
Classification Regulation	882.1540, Class II	882.1540, Class II	882.1540, Class II
Product Code	GZO	GZO	GZO
Indication	<p>QBioScan is indicated for the measurement of galvanic skin response to aid in the assessment of the sudomotor function.</p> <p>The device is intended for use on the general adult population in medical clinics, healthcare practices and out-patient departments of hospitals.</p>	<p>The SUDOSCAN system is a medical device for the measurement of galvanic skin responses.</p>	<p>The SUDOSCAN system is a medical device for the measurement of galvanic skin response to aid in the assessment of sudomotor function.</p> <p>SUDOSCAN is indicated for use in the general adult population.</p>
Operating Characteristics	<ul style="list-style-type: none"> Measures difference in skin conductance. Used to provide feedback to physicians, not to diagnose. Skin Contact Pads measure skin conductance. 	<ul style="list-style-type: none"> Measures difference in skin conductance. Used to provide feedback to physicians, not to diagnose. Skin Contact Pads measure skin conductance. 	<ul style="list-style-type: none"> Measures difference in skin conductance. Used to provide feedback to physicians, not to diagnose. Skin Contact Pads measure skin conductance.
Electrode Surface Area	<p>Hand: 384 cm²</p> <p>Foot: 384 cm²</p> <p>Head: 7 cm²</p>	<p>Hand: 212 cm²</p> <p>Foot: 269 cm²</p> <p>Head: 7 cm²</p>	<p>Hand: 212 cm²</p> <p>Foot: 269 cm²</p> <p>Head: N/A</p>
Electrode Placement (Anatomic Sites)	Hands, Feet, Forehead	Hands, Feet, Forehead	Hands, Feet
Electrode Materials	<p>Head Electrode:</p> <ul style="list-style-type: none"> Stainless Steel with Ag/AgCl layer (cleared electrode) <p>Hand and Foot Electrode:</p> <ul style="list-style-type: none"> AISI 304 Stainless Steel 	<p>Head Electrode:</p> <ul style="list-style-type: none"> Nickel Silver Alloy <p>Hand and Foot Electrode:</p> <ul style="list-style-type: none"> AISI 304 Stainless Steel 	<p>Hand and Foot Electrode:</p> <ul style="list-style-type: none"> AISI 304 Stainless Steel
Skin Conductance Measurement Range	10 - 100 μS/cm ²	10 - 100 μS/cm ²	10 - 100 μS/cm ²

	Proposed Device	Predicate Device	Predicate Device
510(k) Number	N/A	K100233	K141872
Skin Conductance Resolution	1 nS/cm ²	1 nS/cm ²	1 nS/cm ²
Acquisition Duration (total)	120, 300 or 600 seconds	120 seconds	120 seconds
Electrical Output to the skin	4 V max	4 V max	4 V max
Electrical Output Frequency	Continuous	Continuous	Continuous
Electrical Output Unit Duration	1 second	1 second	1 second
Power Density (at electrode)	0.01 µA/mm ²	0.01 µA/mm ²	0.01 µA/mm ²
User Display	Computer Display	VGA Color LCD	VGA Color LCD
User Control	Computer provided with system	Touch screen	Touch screen
Audible Indicators	Internal Computer Speaker and Optional Headphone	Internal Speaker and Optional Headphone	Internal Speaker and Optional Headphone
Output Report	<ul style="list-style-type: none"> • Subject details (patient data) • Indication for referral [entered by examining physician] • Method • Results • Impressions [entered by examining physician] • Measured STC[†] values of the test • 4 average values of 12 STC measurements: <ul style="list-style-type: none"> • <u>Two STC for each Hand:</u> Average value of a minimum of 6 STC measurements • <u>Two STC for each Foot:</u> Average value of a minimum of 6 STC measurements • <u>Head:</u> Average value of a minimum of 6 STC measurements 	<ul style="list-style-type: none"> • Subject details (patient data) • Indication for referral [entered by examining physician] • Method • Results • Impressions [entered by examining physician] • Measured STC[†] values of the test • Two average values of 12 STC measurements: <ul style="list-style-type: none"> • <u>Hand:</u> Average value of 6 STC measurements • <u>Foot:</u> Average value of 6 STC measurements 	<ul style="list-style-type: none"> • Subject details (patient data) • Indication for referral [entered by examining physician] • Method • Results • Impressions [entered by examining physician] • Measured STC[†] values of the test • Two average values of 12 STC measurements: <ul style="list-style-type: none"> • <u>Hand:</u> Average value of 6 STC measurements • <u>Foot:</u> Average value of 6 STC measurements • <u>Head:</u> Average value of 6 STC measurements
Interface	USB from laptop	(USB) Internal	(USB) Internal
Power Source	5 V provided by USB	5 V provided by USB	5 V provided by USB
Electrical Safety Standards	IEC 60601-1 EN 60601-1-2	IEC 60601-1 EN 60601-1-2	IEC 60601-1 EN 60601-1-2 ANSI/AAMI PC69
Electrical Safety Classification	Class II Type BF Applied Part	Class I Type BF Applied Part	Class I Type BF Applied Part

[†] **STC**- Standard Conductance; the terminology used to describe the ionic current measured by the predicate device electrodes

Based on comparisons of device technological characteristics, features, materials, intended use and performance the QBioScan™ has been shown to be substantially equivalent to the commercially available and legally marketed Sudoscan device.

b1 NON-CLINICAL TESTING:

The QBioScan™ device was subjected to the following non-clinical performance testing:

Electrical Safety and Electromagnetic Compatibility (EMC) Testing

The device was submitted for testing and was found to be in compliance with the requirements of IEC 60601-1, 3rd Edition and EN 60601-1-2, 3rd Edition.

Software Verification and Validation Testing

Software verification and validation testing were conducted following the FDA guidance document for software contained in medical devices. The software was considered to be a "moderate" level of concern since a failure or latent flaw could indirectly result in a minor injury to the patient through incorrect or delayed information or through action of the operator.

b2 CLINICAL TESTING:

No Clinical testing was necessary to determine substantial equivalence.

b3 CONCLUSIONS DRAWN FROM TESTING:

Based on information obtained on the predicate device with reference to the design specification, electrical safety / EMC testing and intended use, the QBioScan™ device was subjected to the same type of testing. The results support the conclusion that the QBioScan™ device is substantially equivalent to the Sudoscan device from Impeto Medical.