DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 7, 2014

Pantheon Research
c/o Yolanda Smith
Smith Associates
1468 Harwell Ave.
Crofton, MD 21114

Re: K133980
Trade/Device Name: Pantheon Electrostimulator Models 4c.Pro, 6c.Pro, 8c.Pro, 12c.Pro, 9c3i
Regulation Number: Unclassified
Regulation Name: Electro-Acupuncture Stimulator
Regulatory Class: Unclassified
Product Code: BWK
Dated: October 10, 2014
Received: October 10, 2014

Dear Ms. Smith:

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,

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

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)*
K133980

Device Name
Pantheon Electrostimulator Models 4c.Pro, 6c.Pro, 8c.Pro, 12c.Pro, 9c3i

Indications for Use *(Describe)*
The Pantheon Research Electrostimulator 4c.Pro, 6c.Pro, 8c.Pro, 12c.Pro, & 9c3i are for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

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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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary
**807.92(c)**

**SPONSOR** **807.92(a)(1)**


Company Name: Pantheon Research

Company Address: 626A Venice Blvd
Venice, California 90291

Telephone: 310-822-4965

Contact Person: John Hubacher


Summary Preparation Date: December 13, 2013

**DEVICE NAME** **807.92(a)(2)**

Trade Name: Pantheon Electrostimulator 4c.Pro, 6c.Pro, 8c.Pro, 12c.Pro, & 9c3i
Common/Usual Name: Electro-Acupuncture Stimulator
Classification Name: Electro-Acupuncture Stimulator
Regulation Number**:** Unclassified
Product Code: BWK
Device Class: Unclassified
Panel: Neurology

**PREDICATE DEVICE** **807.92(a)(3)**

Legally Marketed Equivalent Device

| 510k Number | Product | Company |
|---|---|---|
| K081943 | Model ES-130 Electro-Acupuncture Device o | Ito Co., Ltd. |

**DEVICE DESCRIPTION** **807.92(a)(4)**

The Pantheon Research Pro Series electro-acupuncture stimulators are electrical stimulators that introduce calibrated and controlled electrical impulses into acupuncture needles inserted into patients for therapeutic purposes.
These devices are built in 5 models: the 4c.Pro, 6c.Pro, 8c.Pro, 12c.Pro, and 9c3i models.

The Pantheon electro-acupuncture stimulator series does not come equipped with acupuncture needles. The practitioners should select 510(k) cleared needles

**DEVICE INTENDED USE** **807.92(a)(5)**

The intended use of the Pantheon Research Electro-Stimulators (Models 4c Pro, 6c. Pro, 8c. Pro, 12c. Pro, and 9c3i) are electro-acupuncture devices for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

Caution: Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

**COMPARISON OF TECHNICAL CHARACTERISTICS 807.92(a)(6)**

| | **Subject Device: Pantheon Electrostimulators 4c.Pro, 6c.Pro, 8c.Pro, 12c.Pro, 9c3i** | **Predicate Device: Ito ES 130** |
|---|---|---|
| K Number | | K081943 |
| Manufacturer | Pantheon Research | Ito Co., Ltd |
| Trade Name | Pantheon Electrostimulators 4c.Pro, 6c.Pro, 8c.Pro, 12c.Pro, and 9c3i | ES-130 |
| Device Type | Stimulator, Electro-Acupuncture | Stimulator, Electro-Acupuncture |
| Product Code | BWK | BWK |
| Authorized Use | Prescription Use | Prescription Use |
| Indications for Use | The Pantheon Research Electrostimulator 4c.Pro, 6c.Pro, 8c.Pro, 12c.Pro, & 9c3i are for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states. | The intended use of the ES-130 is an Electro-Acupuncture Device for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states. |
| Accessory Attachment Methods | Leads: alligator clips on wires | Leads: alligator clips on wire |
| Voltage | 2.95 Vrms @ 300 ohm; 14.5 Vrms @ 2500 ohm; 24.9 Vrms @ 10000 ohm. | 20 v @ 500 ohms , 30 v @ 10,000 ohms |
| Current: milliampere<br>Microampere: | 5.76 mA r m s @ 300 ohms<br>0 to 600 microamperes | Low: 0-20 mA<br>High: 0-40 mA |
| Max. Power density | .248 W/cm$^2$ @300 ohms, 500hz. | NA |
| Max Current density | 9.78 MA rms @300 ohms, 500 hz | NA |
| Frequency | .5 to 200 Hertz. (Pantheon Electrostimulators 4c.Pro, 6c.Pro, 8c.Pro, 12c.Pro).<br>.5 to 500 Hertz (Pantheon Electrostimulator 9c3i only) | L: 1 ~ 20 Hz<br>M: 20 ~ 150 Hz<br>H: 150 ~ 500 Hz |
| Pulse Width | 400 micro seconds | 250 micro seconds |
| Pulse Shape (Design) | Asymmetric Biphasic Square wave | Asymmetric Biphasic Square Wave |
| Pulse Shape (Measurement) | Asymmetric Biphasic Square wave | Asymmetric Biphasic square wave |

| | | |
|---|---|---|
| Power Supply | 4, 6, 8, 12c.Pro: 2 9v batteries<br>9c3i: 4 9v batteries | One 9 V Battery |
| Rated Power Consumption | DC 18 V @ < 30 ma. | DC 9V (Cannot be connected with AC/DC Converter) |
| Battery Life | 18.8 hours (30mA max. @ a load of 620 ohms) | |
| Buzzer | All yes. Used as machine diagnostic Alarm for safety alert. | No |
| LCD | No. | No |
| Operating Temp:<br>Storage : | 10-40 degrees C<br>10 -60 degrees C | 10 -40 degrees C<br>10 – 60 degrees C |
| Humidity::Use<br>Storage | 30 85%<br>30 – 95% | 30 – 85%<br>30 – 95% |
| Barometric Pressure: Use:<br><br>Storage: | 700-1060 Pa<br><br>700-1060 Pa | 700 – 1060 Pa<br><br>700 – 1060 Pa |
| Safety Features | Device cannot turn ON unless all outputs knobs are first turned OFF. Prevents accidental shocking of patient.<br><br>Multiple internal safety features to prevent electronic malfunction, such as current limiting resisters that are redundant. | None |
| Test Functions | 1) Clip lead tester<br>2) Out put tester, to test if the output is present<br>3) Auto battery tester, test battery automatically and provides warning light and sound if battery is low.<br>4) Manual battery test, allows manual checking of battery level. | None |

**NONCLINICAL AND CLINICAL TEST 807.92(b)**

**SAFETY and EFFECTIVENESS**

Electrical Safety and EMC Testing

IEC 60601-1: Issued:1988/12/30 Ed:2 Medical Electrical Equipment Part 1: General Requirements for Safety; Amendment 1; 1991, Amendment 2; 1995, Corrigendum 1; 1995

IEC 60601-2-10 Medical Electrical Equipment Part : Particular Requirements for the Safety of Nerve and Muscle Stimulators- First Edition; Amendment 1: 09-2001.

EN 60601-1-2:2007
IEC 60601-1-2:2007
Class B for Emissions,
Immunity for Non Life-Supporting Equipment

Biocompatibility
Testing was performed in accordance with ISO 10993-1.

**CONCLUSION** **807.92(b)(3)**

The Pantheon Electrostimulators, 4c.Pro, 6c.Pro, 8c.Pro, 12c.Pro and 9c3i are substantially equivalent to the predicate device in Indications for Use, operating principle and technological characteristics, with the addition of safety features, such as lower current level and safety features for safe use and equipment testing. Electrical Safety and EMC testing to IEC standards, and biocompatibility testing to 10993 has concluded that the device does not introduce significant questions of safety and efficacy and is substantially equivalent to the predicate.