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

October 2, 2014

Navigant Consulting, Inc.
Colleen Hittle
Managing Director
30 S. Wacker Drive, Suite 3100
Chicago, Illinois 60606

Re: K140530
Trade/Device Name: Electro Auricular Device
Regulation Name: Electro Acupuncture Stimulator
Regulatory Class: Unclassified
Product Code: BWK
Dated: August 29, 2014
Received: September 2, 2014

Dear Ms. Colleen Hittle:

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)*
K140530

Device Name
EAD (electro auricular device)

Indications for Use *(Describe)*
The EAD is an electro acupuncture device 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S
Date: 2014.10.02 20:47:21 -04'00'

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510(k) Summary

Submitter & Contact Information

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Date: June 23, 2014

Manufacturer: Key Electronics
2533 Centennial Blvd
Jeffersonville, IN 47130

Trade Name: EAD (electro auricular device)

Common Name: electro acupuncture device

Classification Name(s): BWK – stimulator, electro-acupuncture

Classification Number: Unclassified

Predicate Device(s)

	510(k) Number	Device Name	Submitter Name
Primary Predicate	K050123	P.Stim System	Neuroscience Therapy Corporation
Reference Device	K091875	E-Pulse	Medevice Corporation

Device Description

The EAD system is a battery-operated, single-use device that has a preprogrammed frequency, pulse and duration for the stimulation of auricular point nerve stimulation for pain. The device power supply connects via four (4) stainless steel wires, sheathed in a plastic over-molding, to three (3) needle arrays comprised of four (4) needles each and one (1) needle array comprised of only 1 needle.

The device is powered by one 3 Volt lithium ion battery.

The device modulates a duty cycle between 2 hours on and 2 hours at rest. The maximum performance time frame is 5 days or 120 hours (5 days X 24 hours). Weight is 4 grams including batteries. The power supply dimensions are 36 mm x 17 mm x 7 mm. The needle dimensions are 0.5 mm width x 2 mm length.

Intended Use(s)

The EAD is an electro acupuncture device for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

Technological Characteristics

Appliance: Electro-acupuncture Device
Type description: EAD
Power supply: 1 x 3V battery (Type CR1220 Lithium)
Output: (Load impedance range 1k-10kQ) max. 3.2V, Impulse interval 1000ms, impulse width 1ms, 'ims *I* bipolar), max possible total duration of treatment 5x 24 hours
Protection level: IP20 Type: B
Duty type: approx. 2h duty *I* 2h at rest (periodic duty)
Weight incl. battery: 4g Dimensions: 36 x 16 x 7 mm
Needle Dimensions: 0.5 mm width x 2 mm length

Comparison Table: Applicant Device vs. Predicate Devices

Device Name	EAD	E-Pulse (Reference Device)	P.Stim System (Primary Predicate)
501(k) Number	This Submission	K091875	K050123
Indication for Use	The EAD is an electro acupuncture device for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.	The E-Pulse is an electro acupuncture device for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.	The P-Stim is an electro acupuncture device for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.
Device Description	Battery powered device generates low frequency and continual electrical pulse which are transmitted to new endings of the ear. It allows continued therapy over several days. The device is controlled by a micro processor.	Battery powered unit designed to administer auricular point nerve stimulation treatment for pain therapy over a 96-hour period via electrical pulsing. The device is on for 3 hours and then off for 3 hours. The device is controlled by a micro processor.	A micro stimulation appliance for pain therapy. The device generates low frequency and continual electrical pulse which are transmitted to new endings of the ear. It allows continued therapy over several days. The device is controlled by a micro processor.
Target Population	Patients with acute and chronic pain	Patients with acute and chronic pain	Patients with acute and chronic pain
Human Factors	To be applied by a qualified practitioner of acupuncture	To be applied by a qualified practitioner of acupuncture	To be applied by a qualified practitioner of acupuncture
Where Used	At the clinic and at home	At the clinic and at home	At the clinic and at home
Software Based	Yes	Yes	Yes
Performance	2 hours on/2 hours off; pulses with modulating frequency (1 to 10 Hz)	3 hours on/3 hours off; pulse monophasic at 1 Hz	3 hours on/3 hours off; pulse monophasic at 1 Hz
Power Source	Lithium ion battery	Zinc air battery	Zinc air battery
Duration	Up to 120 hours	96 hours	96 hours

Generator	Attached behind patient ear	Attached behind patient ear	Attached behind patient ear
Leads	Four electrode needle leads	Three leads that can attach to needles	Three leads that can attach to needles
Needles	Titanium straight shaft	Titanium hook shaft	Titanium straight shaft
Shape	Elliptical	Round	Elliptical

Non-Clinical Performance Data

Biocompatibility Testing
The biocompatibility evaluation for the adhesive for the EAD device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The EAD adhesive is considered tissue contacting for a duration of less than 30 days. The other patient contacting materials contained in the subject device are unchanged from the P-Stim predicate device.

Electrical Safety and Electromagnetic Compatibility (EMC)
Electrical safety and EMC testing were conducted on the EAD device. The system complies with the IEC 60601-1 and IEC 60601-2-10 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing
Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "minor" level of concern, since a failure or latent flaw in the software could not directly result in serious injury or death to the patient or operator.

Sterility/Shelf Life
Sterilization Validation was conducted on the EAD device needles and wiring harness using the VDMAX25 method according to ISO 11137-2 and ISO 11737-2. Performance and stability of the EAD packaging was validated in accordance with ISO 11607-1 and Accelerated aging of the EAD was performed in accordance with ASTM F1980-07. Packaging qualifications are according to ISO 11607-1 and machine qualifications for the sealing process are according to ISO 11607-2.

Conclusion

The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that the EAD device should perform as well as the predicate device in the specified use conditions.