DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 27, 2015

Synapse Electroceutical Limited
% Mary Dadone
Martin, Blank & Associates
3905 Rhode Harbor Rd
Edgewater, Maryland 21037

Re: K143198
Trade/Device Name: Synapse Transcutaneous Electrical Stimulation Device
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: GZJ
Dated: April 27, 2015
Received: April 27, 2015

Dear Ms. Dadone,

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,

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)*
K143198

Device Name
Synapse Transcutaneous Electrical Stimulation Device

Indications for Use *(Describe)*
The Synapse Transcutaneous Electrical Stimulation Device is intended for use for the symptomatic relief and management of chronic intractable pain. The Synapse Transcutaneous Electrical Stimulation Device may be used during sleep.

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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510(k) Summary

SPONSOR

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Date Prepared 29 Sep 2014

APPLICATION CORRESPONDENT

Mary Dadone for Martin, Blanck & Associates
3905 Rhode Harbor Rd
Edgewater, MD 21037
+1 301 706 0731

DEVICE NAME

Trade Name	Synapse Transcutaneous Electrical Stimulation Device
Common Name	Transcutaneous Electrical Nerve Stimulator
Classification Name	Transcutaneous Electrical Nerve Stimulator for Pain Relief (21 CFR 882.5890, Product Code GZJ)

PREDICATE DEVICE

NeuroMetrix SENSUS™ (K130919)

DEVICE DESCRIPTION

The function of the Synapse Transcutaneous Electrical Stimulation Device is to apply a series of pre-programmed micro-currents of varying frequency, amplitude and duration to the patient via electrode pads. A micro-controller is used to set the current demands to a linear current controller implemented solely in hardware.

The Synapse Transcutaneous Electrical Stimulation Device is oval shaped and measures approximately 7 cm wide by 4 cm high by 2 cm deep. It is activated by pressing the On/Off button. There is single set program which runs in specific sequence for 48 hours after which time the unit will turn itself off and should be replaced with

another unit until the end of the prescribed course of treatment. The devices are packaged in quantities of 6 so that the total treatment duration is 12 days.

The Synapse Transcutaneous Electrical Stimulation Device has an LED light which indicates operational status: unit off, treatment active, treatment dormant (waiting for next active session), or current too low (e.g., interruption during treatment due to poor skin contact of the electrodes)

Only Covidien's Uni-Patch electrode series are recommended for use with the Synapse Transcutaneous Electrical Nerve Stimulator. These electrodes are cleared for marketing by the FDA and are provided with stimulating electrode hydrogel (K915333); Synapse Order Code EP84910)

INDICATIONS USE

The Synapse Transcutaneous Electrical Stimulation Device is intended for use for the symptomatic relief and management of chronic intractable pain. The Synapse Transcutaneous Electrical Nerve Stimulator may be used during sleep.

COMPARISON TO PREDICATE

The table below provides a comparison of the Synapse Transcutaneous Electrical Stimulation Device to the NeuroMetrix SENSUS™ (K130919) predicate.

Parameter	Synapse Transcutaneous Electrical Stimulation Device	NeuroMetrix, Inc SENSUS Unit
Power Source(s)	Non rechargeable 3V Lithium maganese coin cell battery	1 rechargeable 3.7V Lithium-ion battery
Method of Line Current Isolation	n/a – no connection to line current	Physically isolated; device cannot connect to electrodes and battery recharger concurrently
Number of Output Modes	One (1)	One (1)
Number of Output Channels	One (1)	One (1)
Regulated Current or Regulated Voltage?	Current	Current
Software/Firmware/Microprocessor Control?	Yes	Yes

Parameter	Synapse Transcutaneous Electrical Stimulation Device	NeuroMetrix, Inc SENSUS Unit
Automatic Overload Trip?	No – hardware is limited by design not to accept demand for other currents	Yes
Automatic No-Load Trip?	User warned via LED flash rate	Yes
Automatic Shut Off?	Yes	Yes
User Override Control?	Yes	Yes
Indicator Display:	Yes	Yes
Timer Range	48 hours	60 minutes
Compliance with Voluntary Standards?	IEC60601-1, IEC 60601-1-2	IEC60601-1, IEC 60601-1-2
Weight (lbs., oz.)	0.088 lbs (1.4 oz)	2.9 oz
Dimensions (in.) [W x H x D]	7cm x 4 cm x 2cm	18 mm x 63mm x 176 mm
Housing Materials and Construction	Makrolon™, injection moulded	Plastic, Velcro straps (nylon)

As shown in the above table, the Synapse Transcutaneous Electrical Stimulation Device has similar characteristics to the predicate device. The primary difference is that the Synapse Transcutaneous Electrical Stimulation Device is a non-reusable unit that provides a pre-programmed treatment regime whereas the predicate device is a re-useable, rechargeable device. These differences and the minor differences in size, weight, and materials do not raise any new types of safety or effectiveness questions.

NON-CLINICAL TESTING

Test results included in the 510(k) demonstrate conformance with the electrical safety and electromagnetic compatibility requirements of IEC 60601-1 Medical electrical equipment – part 1: General requirements for basic safety and essential performance 2005 (3rd edition) plus Amendments 1:2006 and 2:2007 and IEC 60601-1-2 Medical Electrical Equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests (edition 2007).

CONCLUSION

The verification, validation, and performance data presented in this 510(k) pre-market notification demonstrate that the Synapse Transcutaneous Electrical Stimulation Device is substantially equivalent to and as safe and effective as the predicate device.