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

March 9, 2017

Dyansys Inc
Srini Nageshwar
CEO
300, North Bayshore Boulevard
San Mateo, California 94401

Re: K170391
Trade/Device Name: ANSiStim-PP
Regulatory Class: Unclassified
Product Code: BWK
Dated: February 4, 2017
Received: February 8, 2017

Dear Srini Nageshwar:

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,

William J. Heetderks -S

Digitally signed by William J. Heetderks -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -S
Date: 2017.03.09 10:27:14 -05'00'

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)*
K170391

Device Name
ANSiStim - PP

Indications for Use *(Describe)*
The ANSiStim-PP 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.87 and 21 CFR 807.92.

510(k) Number: K170391

1. Applicant Information:

Date Prepared:

Name: DyAnsys, Inc
Address: 300, North Bayshore Boulevard,
San Mateo, CA 94401, USA
Contact Person: Srini Nageshwar
Phone Number: 408.480.4700
Facsimile Number: (650)556-1621

Device Information

Classification :Unclassified
Trade Name :ANSiStim®-PP
Common Name :Electro-acupuncture device
Classification Name :Stimulator, Electro-acupuncture
Product Code :BWK

2. Predicate Device:

K Number: K141168
Model Name: ANSiStim
Manufacturer: DyAnsys Inc.,

3. Device Description:

The ANSiStim®-PP is a wearable, battery-operated device that is designed to administer continuous low-level electrical pulses to the ear over four days / 96 hours from the time of activation of the device. The electrical pulse from the device will be delivered to the stimulation point on the ear through a set of wire assembly and Stimulation needles. Three zinc air batteries with 1.4 V each provides the required stimulation energy for a maximum of 96 hours. There are three Stimulation needles and one ground electrode - which constitute of a needle and lead/ wire with the snap-fit ring. The stimulation needles are inserted at three specific points, which have the ability to stimulate the auricular cranial nerves. The ground electrode is inserted at one specific point (constant in all treatments) which forms the functional earthing to the device. The device is also provided with a bottom ground.

There are three options available for using the ground terminal in the device. Either the ground electrode or the bottom ground can be used. Or both the ground electrode and bottom ground can be used together.

This constant current source guarantees equivalent stimulation energy regardless of the individual impedance of the skin. The treatment period varies based on the severity of the pain in the

individual.
The stimulation pattern consists of 1 Hz single pulses with square waveform. The current direction is inverted every second pulse, which is intended to avoid polarization effects. To minimize the risk of adaption or tolerance to the electrical stimulation, stimulation is applied for 3 hours, followed by a pause of 3 hours.

A 3-pin connector is provided, which is used to check the output voltage of the device once it is activated and before applying to the patient with any one of the voltage measuring devices available in the market with the appropriate regulatory compliance.

4. Intended Use:

The ANSiStim®-PP is as an electro-acupuncture device for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

5. Comparison to Predicate Device:

The DyAnsys, Inc ANSiStim®-PP device is substantially equivalent to it's own legally marketed predicate device ANSiStim (K141168). It was evaluated through Performance and Non-Clinical testing.

MODEL NAME	ANSiStim® (K141168)	ANSiStim®-PP (Subject)	JUSTIFICATION ON SAFETY & EFFECTIVENESS VARIATIONS
MANUFACTURER	DyAnsys Inc	DyAnsys Inc	NA
INTENDED USE	The ANSiStim® is as an electro-acupuncture device for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.	The ANSiStim® is as an electro-acupuncture device for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.	NA
PATIENT POPULATION	Adults	Adults	NA
SHAPE	Oval	Rectangle	NA
DIMENSION, mm	63*28*8 mm	47*22*1 mm	NA
WEIGHT, Kg	5 gm (including battery)	5 gm (including battery)	NA
NEEDLE DIMENSIONS, mm	0.4*2 mm (width*length)	0.4*2 mm (width*length)	NA
WIRE ASSEMBLY	3 nos of Molded SS wire with snap-fit ring constitute a single assembly	4 nos of Molded SS wire with snap-fit ring. Where 3 nos constitute a single assembly for Stimulation and the other one separate SS wire will act as a ground electrode.	
GROUND TERMINAL	Bottom Ground	Either of these two or both can be used as a ground terminal. 1. Bottom Ground	

		2. Ground Electrode	
CONNECTOR	No	A 3-pin connector is used to check the output voltage of the ANSiStim®-PP once it is activated and before applying it to the patient.	Any voltage measuring device with appropriate regulatory compliance alone can be used.
POWER:			
FREQUENCY	1Hz	1Hz	NA
CURRENT	~1mA	~1mA	NA
WAVEFORM	Square Pulse	Square Pulse	NA
(ENERGY SOURCE) BATTERY OPERATION	Yes	Yes	NA
BATTERY TYPE	Zinc Air batteries, AC A10	Zinc Air batteries, P10	NA
BATTERY CAPACITY	100 mAh	100 mAh	NA
NO. / VOLTAGE	3*1.4V	3*1.4 V	NA
DUTY CYCLE	3 hours ON/ 3 hours OFF	3 hours ON/ 3 hours OFF	NA
OPERATING TIME, HOURS	96 h	96 h	NA
ENVIRONMENTAL			
OPERATING TEMPERATURE	5ºC to 45ºC	5ºC to 45ºC	NA
OPERATING HUMIDITY (NON CONDENSING)	40% to 80%	40% to 80%	NA
ENVIRONMENT OF USE	Clinics, Hospital and Home environments	Clinics, Hospital and Home environments	NA
STERILIZATION	EtO Sterilization	EtO Sterilization	NA
RE-USE	Single use Device	Single use Device	NA
PACKAGE	The ANSiStim device and its accessories are packed in a blister. This is then placed in a carton box. Each carton box has ten device.	Same	NA
ACCESSORIES	• ANSiStim® device with inserted non-activated batteries. • Cover of the ANSiStim® • Sterile pack of Needles for use with the ANSiStim®. • Adhesive to fasten the needles. • Adhesive for the ANSiStim® • device. • Alcohol Swab • Instructions for Use	• ANSiStim®-PP device with inserted non-activated batteries. • Cover of the ANSiStim®-PP • Sterile pack of Needles for use with the ANSiStim®-PP. • Adhesive to fasten the needles. • Adhesive for the ANSiStim®-PP • device. • Alcohol Swab • Instructions for Use	NA
PLANNING & PURCHASE			
WARRANTY	NA	NA	Since it is a single use device.

Difference Between the Legally Marketed Predicate Device:

- Difference in Components
    1. The micro-controller which is used to control the electrical stimulation pulse has been changed from that of used in the predicate device.
    2. The energy source (battery) has been replaced by its equivalent to that of the predicate device.
    3. An additional ground terminal is provided.
    4. A 3-pin connector is provided additionally, which is used to check the voltage of the device.

These differences does not affect the safety and effectiveness of the device.

6. Performance Testing Summary

The ANSiStim®-PP device and its components are subjected to performance testing to validate the effectiveness of each unit. The final product testing is performed to verify and compare the effectual output along with that of the predicate device. The functional test is performed for 96 hours to monitor the 3 hours ON state followed by 3 hours OFF state. The pulse width, pulse duration, amplitude and current values are captured for the ANSiStim®-PP device. The ANSiStim®-PP has equivalent Performance specifications when compared to the predicate device.

All the patient contacting materials of the ANSiStim®-PP are similar to the predicate device.

7. Compliance with Standards

The ANSiStim complies with the following standards

1. IEC 60601-1
2. IEC 60601-1-2
3. ISO 10993-1
4. ISO 10993-5
5. ISO 10993-6
6. ISO 10993-7
7. ISO 10993-10
8. ISO 10993-11
9. ISO 11135

8. Sterilization Testing Summary

The needle package was subjected to Bio-burden test. The Needle packs are exposed to EtO Sterilization to curtail the presence of microorganisms and to achieve the defined sterility assurance level (SAL). During the sterilization validation process the biological indicators are used to ensure the desired sterility assurance level. These BIs were placed at the appropriate location, where the sterilizing conditions are the most difficult to achieve. These needle packages carry a chemical indicator on the rear side which indicates the exposure to EtO. The sterility test performed on the needles indicates that there is no turbidity. The residual risk report carried out on the sterilized

needle packs evidenced that the results are inline with standards requirement. All Sterilization testing was performed in accordance with ISO 11135:2014-Sterilization of healthcare products- ethylene oxide, ISO 11140-1:2005/(R) 2010 Sterilization of healthcare products- chemical indicators, ISO 10993-7:2008/(R) 2012 Biological evaluation of medical devices- ethylene oxide sterilization residuals, ISO 11737-1:2006/(R) 2011 Sterilization of medical devices- Microbiological methods- Part 1: Determination of a population of microorganisms on products, ISO 11737-2: 2009 Sterilization of medical devices- Microbiological methods- Part2: Tests of Sterility performed in the definition, validation and maintenance of a Sterilization process and ISO 11138-2:2006/(R) 2010– Sterilization Of Healthcare Products-Biological Indicators- Part2: Biological Indicators for ethylene oxide Sterilization Processes.

8. Non-Clinical Testing Summary

The bench test has been performed and found that the ANSiStim®-PP met all the requirements specifications and standards requirements. The testings includes the following:

1. MEE testing as per IEC 60601-1
2. EMI/EMC testing as per IEC 60601-1-2
3. Biocompatibility testing as per ISO 10993
4. Performance testing

9. Conclusion

Hence it is concluded that by demonstrating the Performance testing and with the Indications For Use, Environment for Use, Biocompatibility and compliance with the same harmonized standards, the product ANSiStim®-PP is substantially equivalent to the predicate device that was cleared under K141168.