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

May 15, 2015

DyAnsys Inc.
Srini Nageshwar
CEO DyAnsys Inc.
Contact Address

Re: K141168
Trade/Device Name: ANSiStim™
Regulation Name: Electro-Acupuncture Stimulator
Regulatory Class: Unclassified
Product Code: BWK
Dated: April 20th 2015
Received: May 12, 2015

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 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 on last page.

510(k) Number *(if known)*

K141168

Device Name
ANSiStim™

Indications for Use *(Describe)*

The ANSiStim™ 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)*

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 21 CFR 807.87 and 21 CFR 807.92.

510(k) Number: __K141168___

1. Applicant Information:

Date Prepared:	30th January 2015
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™
Common Name	:Electro-acupunture device
Classification Name	:Electro-acupuncture stimulator
Product Code	:BWK

2. Predicate Device:

K Number: K050123
Model Name: P-Stim
Manufacturer: Neuro Science Therapy Corp.

3. Device Description:

The ANSiStim™ is a wearable battery-operated device that is designed to administer continuous low-level electrical pulses at the ear over four days. The stimulation needles are inserted at three specific points, which have the ability to stimulate the acupoints in the human body. Three zinc air batteries with 1.4 V provide the required stimulation energy for a maximum of 96 hours. This constant current source guarantees equivalent stimulation energy regardless of the individual impedance of the skin.

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.

4. Intended Use:

The ANSiStim™ is 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™ device is substantially equivalent to the predicate device P-STIM (K050123). It was evaluated through Performance, Biocompatibility and Sterilization testing. The ANSiStim™ and the predicate device are both transcutaneous electrical nerve stimulators with a single output channel and mode with similar pulse width and frequency.

Table 1

MODEL NAME	P-STIM (K050123)	ANSiStim	JUSTIFICATION ON SAFETY & EFFECTIVENESS VARIATIONS
INDICATION OF USE (INTENDED USE)	P-STIM is an electro-acupuncture device for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.	The ANSiStim™ is an electro-acupuncture device for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.	NA
DIMENSION, mm	63*28*8 mm	63*28*8 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
POWER			
FREQUENCY	1Hz	1Hz	NA
CURRENT	~1mA	~1mA	NA
WAVEFORM	Square Pulse	Square Pulse	NA
BATTERY OPERATION	Yes	Yes	NA
BATTERY TYPE	Zinc Air batteries, AC A10	Zinc Air batteries, AC A10	NA
NO. / VOLTAGE	3*1.4V	3*1.4V	NA
OPERATING TIME, HOURS	96 h	96 h	NA
ENVIRONMENTAL			
OPERATING TEMPERATURE	5°C to 30°C	5°C to 45°C	Improved specification validated by test report.
OPERATING	40% to 60%	40% to 80%	Improved specification

HUMIDITY (NON CONDENSING)			validated by test report.
PLANNING & PURCHASE			
WARRANTY	NA	NA	Since it is a single use device.

6. Performance Testing Summary

The ANSiStim™ device and its components are subjected to performance testing to validate the effectiveness of each unit. The tests performed are: (i) Physical Test- Bare Board test, (ii) Functional Test for ANSiStim™ and (iii) Comparative Performance Testing: ANSiStim™ Vs Predicate Device- wire assembly testing, PCB assembly testing and final product testing. 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™ device. A comparative performance analysis is performed with the ANSiStim™ and its predicate device.

7. Biocompatibility Testing Summary

All biocompatible testing was performed in accordance with ISO 10993: 2009 Biological Evaluation of Medical Devices.

7.1.Test Reports for Biocompatibility:

The following tests were done on the ANSiStim™ needle and the wire assembly:

A) Acute Systemic Toxicity study in Swiss albino mice as per Biological Evaluation of medical devices- Part 11: Tests for systemic toxicity [ISO 10993-11:2006 (E)].

B) Subcutaneous Implantation (1- week) study in Wistar rats as per Biological Evaluation of medical devices- Part 6: Tests for local effects after implantation [ISO 10993-6:2007].

C) Skin Sensitization Study in Guinea pigs as per Biological Evaluation of medical devices- Part 10: Tests for irritation and skin sensitization [ISO 10993-10:2010(E)].

D) Intracutaneous Reactivity Test in New Zealand White rabbits as per Biological Evaluation of medical devices- Part 10: Tests for irritation and skin sensitization [ISO 109933-10: 2010(E)].

E) Test for in vitro cytotoxicity: Elution method as per Biological Evaluation of medical devices- Part 5 Tests for in vitro cytotoxicity [ISO 10993-5:2009 (E)].

7.2.Test Reports for 3M Material:

The following tests were carried out by 3M as seen in the Product Clinical Data Summary:

F) Foam Pad (9776): Biocompatibility Testing performed as per ISO 10993-1 : In Vitro Cytotoxicity (Agar Overlay), Repeat Skin Irritation in Albino Rabbits, Repeated Insult Patch Test (Draize) in Humans, 21-day Cumulative Irritation in Humans, Primary Skin Irritation Test, Ocular Irritation Study, Cytotoxicity-Agarose Overlay, Solid.

G) Adhesive Tape (Oval & wing sticker, 1533L): Biocompatibility Testing performed as per ISO 10993-1: In Vitro Cytotoxicity, Guinea Pig Sensitization, Repeated Insult Patch Test (Draize) in Humans, 21-day Cumulative Irritation in Humans, Primary Skin Irritation Test.

H) Conductive Adhesive (9880): Biocompatibility Testing performed as per ISO 10993-1: In Vitro Cytotoxicity (Agar Overlay), Repeat Skin Irritation in Albino Rabbits, Repeated Insult Patch Test (Draize) in Humans, 21-day Cumulative Irritation in Humans.

8. Sterilization Testing Summary

The needle package was subjected to Bio-burden test. The Needle packs are exposed to ETO Sterilization using bio-burden approach to curtail the presence of micro-organisms and to achieve the defined sterility assurance level (SAL). During the sterilization 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.

9. Conclusion

Hence it is concluded that by demonstrating Performance testing, Biocompatibility and Sterilization testing, the product ANSiStim™ is substantially equivalent to the predicate device P-STIM that was cleared under K050123.

As per the performance testing results and observations we can conclude that the ANSiStim™ sub-system functionality is effectual, hence the final product is found working without any discrepancy in the output. The comparative performance testing highlights the effectiveness of ANSiStim™ with reference to the Predicate Device.

As per biocompatibility the test item ANSiStim™ did not show any signs of toxicity, non-cytotoxic, no induced sensitization, non-irritant and intracutaneous reactivity within limits throughout the experimental period. Hence the test lab concluded that the test item ANSiStim™ supplied by M/s DyAnsys India Pvt Ltd meets the requirements of **Biological Evaluation of Medical Devices** under the conditions of the present study.

Table 2

Test	Results	Conclusion
Acute Systemic Toxicity study in Swiss albino mice test	**Mortality & Morbidity:** No signs **Body Weight Recording:** All animals showed increase in body weight **Clinical Observation:** No signs **Necropsy:** All animals were euthanized by carbon dioxide **Gross Pathology, Clinical Pathology and Histopathology:** No signs	No systemic toxicity
Subcutaneous Implantation (1-week) study is Wistar rats test	**Mortality & Morbidity:** No signs **Body Weight Recording:** All animals showed increase in body weight **Clinical Observation:** No signs **Gross Pathology, Clinical Pathology and Histopathology:** The average difference obtained from the biological response of the test site and control site is 0.4.	Non-irritant
Skin Sensitization	**Mortality & Morbidity:** No signs **Body Weight Recording:** All animals showed increase in	No sensitization reactions

Study in Guinea pigs test	body weight **Grading of Skin Reactions:** No sensitization reactions **Necropsy:** All animals were euthanized by carbon dioxide	
Intracutaneous Reactivity Test in New Zealand White rabbits test	**Mortality & Morbidity:** No signs **Body Weight Recording:** All animals showed increase in body weight **Clinical Observation:** No signs **Necropsy:** All animals were euthanized by pentobarbital injection **Scoring of Skin Reaction:** No intracutaneous reactivity	No intracutaneous reactivity
In vitro cytotoxicity: Elution method test	The cultures treated with the test item extracts in different dilutions are graded as 0.	Non-cytotoxic

The sterilization and shelf-life section includes the following process for each batch:

- EtO sterilization for needle assembly with the parameters as arrived.
- Sterility assurance level ensured by using appropriate biological indicator during ETO sterilization process.
- Each batch of needle assembly is subjected to bio-burden test, sterility test and residual risk test.
- Shelf-life of sterilized pack is evaluated and confirmed through necessary testings. Also Transportation and Distribution study has been conducted.