May 2, 2018

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

Re: K173861
Trade/Device Name: Drug Relief
Regulation Number: 21 CFR 882.5896
Regulation Name: Percutaneous Nerve Stimulator For Opiod Withdrawal
Regulatory Class: Class II
Product Code: PZR
Dated: April 18, 2018
Received: April 20, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

William J. Heetderks -S
2018.05.02 15:36:03 -04'00'

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K173861

Device Name
Drug Relief

Indications for Use *(Describe)*
The Drug Relief is a percutaneous nerve field stimulatory (PNFS) system, that can be used as an aid to reduce the symptoms of opioid withdrawal, through application to branches of Cranial Nerves V, VII, IX, and X, and the occipital nerves identified by transillumination.

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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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: K173861

**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 : Class II

Trade Name : Drug Relief

Classification Name : Percutaneous nerve stimulator for substance use disorders

Product Code : PZR

**Predicate Device:**

DEN Number: DEN170018
Model Name: NSS-2 BRIDGE
Manufacturer: Innovative Health Solutions, Inc.

**Device Description:**

The Drug Relief™ is designed to aid in the treatment of opiate withdrawal symptoms by the method of electrical stimulation at the auricular stimulation points. The Drug Relief is a wearable, battery-operated device that is designed to administer periodical low-level electrical pulses to the ear over five days / 120 hours (2 hours ON/1 minute OFF) from the time of activation of the device.

The electrical pulse from the device will be delivered to the branches of Cranial Nerves 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 120 hours. There are three Stimulation electrodes 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 cranial nerves. The ground electrode is inserted at one specific point (constant in all treatments) which forms the functional earthing to the device.

This constant current source guarantees equivalent stimulation energy regardless of the individual impedance of the skin.

The stimulation pattern consists of rectangular pulses with differing inter-pulse intervals.

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.

**Intended Use:**

The Drug Relief is a percutaneous nerve field stimulator (PNFS) system, that can be used as an aid to reduce the symptoms of opioid withdrawal, through application to branches of Cranial Nerves V, VII, IX and X, and the occipital nerves identified by transillumination.

**Comparison to Predicate Device:**

The DyAnsys, Inc Drug Relief device is substantially equivalent to it's own legally marketed predicate device NSS-2 BRIDGE (DEN 170018). It was evaluated through Performance and Non-Clinical testing.

| MODEL NAME | Drug Relief (Subject) | NSS-2 BRIDGE (DEN 170018) |
|---|---|---|
| MANUFACTURER | DyAnsys Inc | Innovative Health Solutions, Inc. |
| INDICATIONS FOR USE | The Drug Relief is a percutaneous nerve field stimulator (PNFS) system, that can be used as an aid to reduce the symptoms of opioid withdrawal, through application to branches of Cranial Nerves V, VII, IX and X, and the occipital nerves identified by transillumination. | The NSS-2 BRIDGE is a percutaneous nerve field stimulator (PNFS) system, that can be used as an aid to reduce the symptoms of opioid withdrawal, through application to branches of Cranial Nerves V, VII, IX and X, and the occipital nerves identified by transillumination. |
| PATIENT POPULATION | Adults | Adults |
| SHAPE | Rectangle | Rectangle |
| DIMENSION, mm | 50*23*7 mm | 36*16*7 mm |
| WEIGHT, Kg | 6 gm (including battery) | 4 gm |
| DEVICE ADHESIVE | The device's foam pad is connected to the adhesive – gel pad | Tegaderm is used to fasten the device. |
| NEEDLE DIMENSIONS, | 0.4*2 mm (width*length) | 0.5mm width x 2mm length |

| | | |
|---|---|---|
| mm | | |
| WIRE ASSEMBLY | 4 units of wire with snap-fit ring.<br>Where 3 nos constitute a single assembly for Stimulation and the other one separate wire will act as a ground electrode. | One stainless steel wire with four stimulation needles and two stainless steel wires with one stimulation needle each.<br>There is one ground wire with one needle. |
| WIRE ASSEMBLY TYPE | Wire assembly, without stimulation needles soldered with the pulse generator. | Wire assembly is connected with the stimulation needles as one end and has the facility to connect with the pulse generator. It is sterilized and packed separately. |
| VOLTAGE MEASUREMENT FEASIVLITY | A 3-pin connector provided to measure the output voltage of the device once it is activated. | Not feasible.<br>There is no provision to measure the voltage. Hence not feasible. |
| **POWER:** | | |
| FREQUENCY | Pulses with modulating frequency (1 Hz - 10 Hz) | Pulses with modulating frequency (1 Hz - 10 Hz) |
| WAVEFORM | Rectangular pulse | Rectangular pulse |
| (ENERGY SOURCE) BATTERY OPERATION | Yes | Yes |
| BATTERY TYPE | Zinc Air batteries, P10 | Lithium ion battery, CR1220 |
| BATTERY CAPACITY | 100 mAh | 40 mAh |
| NO. / VOLTAGE | 3*1.4 V | 1*3 V |
| PULSE WIDTH | 0.980mSec | 0.980mSec |
| OPERATING TIME, HOURS | 120 hrs (5 days), 2 Hours ON (Periodically) | 120 hrs (5 days), 2 Hours ON (Periodically) |
| **ENVIRONMENTAL** | | |
| OPERATING TEMPERATURE | 5ºC to 45ºC | 5ºC to 30ºC |
| OPERATING HUMIDITY (NON CONDENSING) | 40% to 80% | 40% to 60% |
| ENVIRONMENT OF USE | Clinics, Hospital and Home environments | Clinics, Hospital and Home environments |
| STERILIZATION | EtO Sterilization | Irradiation (Gamma) |
| RE-USE | Single use Device | Single use Device |
| SHELF LIFE | 6 Months | 12 months |
| **PLANNING & PURCHASE** | | |
| WARRANTY | NA | NA |

| | | |
|---|---|---|
| **Pulse Generator** | | |
| Battery Type and Voltage (V) | Zinc Air batteries, P10 | Lithium ion battery, CR1220 |
| Voltage Controlled? | Yes | Yes |
| Software Controlled? | Yes | Yes |
| Weight (grams) | 6 g | 4 g |
| Dimensions (mm) | 50*23*7 mm | 36*16*7 mm |
| **Electrode Needle Arrays** | | |
| Number of leads | 4 | 4 |
| Lead type | 1 Single needle in all the 4 leads | One stainless steel wire with four stimulation needles and two stainless steel wires with one stimulation needle each. There is one ground wire with one needle. |
| Dimensions of each needle (width and length in mm) | 0.4 mm width x 2 mm length | 0.5 mm width x 2 mm length |
| Surface Area of needle ($cm^2$) | 0.0201 $cm^2$ | 0.0276 $cm^2$ |
| Needle Material | Titanium | Titanium |
| **System Characteristics (Output Specs)** | | |
| Max Charge Density (microcoulomb/$cm^2$) Per needle | 65.67 @ 1K ohm<br>7.96 @ 10K ohm | 48.91 @ 1K ohm<br>5.79 @ 10K ohm |
| Max Average Power Density ($W/cm^2$) | 0.346 @ 1K ohm<br>0.0509 @ 10K ohm | 0.2645 @ 1K ohm<br>0.0371 @ 10K ohm |

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

**Performance Testing Summary**

The Drug Relief 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 120 hours to monitor the continuous performance. The pulse width, pulse duration, amplitude and current values are captured for the Drug Relief device. The Drug Relief has equivalent Performance specifications when compared to the predicate device.

All the hardware components, form factors, material for sterilization and patient contacting materials of the Drug Relief are similar to the 510(K) cleared device ANSiStim-PP (K170391).

**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

**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 in-line 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. Non-Clinical Testing Summary

The bench test has been performed and found that the Drug Relief 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

## 10. 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 Drug Relief is substantially equivalent to the predicate device NSS-2 BRIDGE.