June 6, 2022

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

Re: K221231
Trade/Device Name: Drug Relief v1
Regulation Number: 21 CFR 882.5896
Regulation Name: Percutaneous nerve stimulator for substance use disorders
Regulatory Class: Class II
Product Code: PZR
Dated: June 1, 2022
Received: June 2, 2022

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Pamela Scott
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221231

Device Name
Drug Relief v1

Indications for Use *(Describe)*
The Drug Relief v1 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.

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.

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DyAnsys®

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: K221231

I. SUBMITTER

Date Prepared:	May 26th 2022
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

II. DEVICE INFORMATION

Trade Name:	Drug Relief v1
Classification Name:	Percutaneous nerve stimulator for substance use disorders (21 CFR 882.5896)
Common Name:	Percutaneous nerve stimulator
Device Class:	Class II
Product Code:	PZR

III. PREDICATE DEVICE

Model Name: Drug Relief v1 – (K211971)
Manufacturer: DyAnsys Inc.,

The predicate device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Drug Relief v1 is designed to aid in the treatment of symptoms by the method of cranial electrical stimulation at the auricular stimulation points. The Drug Relief v1 is a wearable, battery-operated device that is designed to administer periodical low level electrical pulses to the ear over five days / 120 hours 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 provide the required stimulation energy for 120 hours. There are three stimulation electrode and one ground electrode which constitute of a titanium 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.

The device is rectangular in shape and designed to fit comfortably on the neck. The biocompatible adhesive ensures that the device maintains contact with the skin during normal use. The adhesive fasteners ensure that the electrode needles and the entire device stay in place in a secure manner.

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

V. INDICATIONS FOR USE

The Drug Relief v1 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 Indications for Use statement of Drug Relief v1 is identical to that of the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Drug Relief v1 device has identical intended use, indications for use, population, application of the device, environment of use as that of the predicate device. The auricular stimulation device stimulates the cranial nerves for reduction of symptoms associated with opioid withdrawal and produces a therapeutic effect. The determination of substantial equivalence is based on the identical fundamental technological and operational characteristics between the subject and identified predicate device.

Table 6.1: Comparison of Technological Characteristics

MODEL NAME	**Drug Relief v1 (Subject)**	**Drug Relief v1 (K211971 - Predicate)**
MANUFACTURER	DyAnsys Inc.	
Intended Use / Indications for Use Statement		
INTENDED USE	Short-term electrical stimulation therapy as an aid in the reduction of opioid withdrawal symptoms.	
INDICATIONS FOR USE	The Drug Relief v1 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	
SINGLE USE ELECTRODES	Yes	

DURATION OF PATIENT CONTACT (days)	5	
TECHNOLOGICAL CHARACTERISTICS		
PULSE GENERATOR		
PRODUCT DIMENSION (mm x mm x mm)	38 * 21 * 10	
MASS (g)	8 g (including battery)	
PRODUCT SHAPE	Rectangle	
POWER		
FREQUENCY (Hz)	1 - 10	
WAVEFORM	Biphasic with Rectangular Pulse	
BATTERY TYPE	P13 Zinc Air batteries that are non-rechargeable	
BATTERY CAPACITY	310 mAh	
NO. x VOLTAGE (V)	3 x 1.4 V	
PULSE WIDTH(ms)	0.980	
DUTY CYCLE	2 hours ON / 1 min OFF	
TYPICAL BATTERY OPERATING TIME (hours)	120	
ENVIRONMENTAL		
OPERATING TEMPERATURE	5 °C to 45 °C	
OPERATING HUMIDITY	40% to 80%	
ENVIRONMENT OF USE	Clinics, Hospital and Home environments	
STERILIZATION OF ELECTRODES	EtO Sterilization	
RE-USE	Single use Device	
SHELF LIFE	12 months	6 months
ACCESSORIES	• Drug Relief v1 device with inserted non-activated batteries. • Cover of the Drug Relief v1 • Sterile pack of needles for use with the Drug Relief v1 • Adhesive to fasten the needles • Adhesive for the Drug Relief v1 device. • Instructions for Use	

To summarize, the energy source in the form of P13 batteries, device design (form factor), material type, chemical composition of all the components are unchanged and remain identical to those of the predicate device.

Table 6.2: Comparison of System Characteristics

System Characteristic	Drug Relief v1 (Subject)	Drug Relief v1 (K211971 - Predicate)
Pulse Generator		
Software Controlled	Yes	
Mass (g)	8 g	
Dimensions(mm)	38 * 21 * 10	
Housing Material	ABS Plastic Material	
Electrode Needle Arrays		
Introduction Method	Percutaneous	
Tissue Contact	Skin/Tissue	
Electrode Configuration	Single needle in all the 4 leads	
Electrode Type	Percutaneous fine needle	
Number of leads	4 (3 signal and 1 ground)	
Needle Dimensions (mm x mm)	0.4 x 2 (diameter x length)	
Surface area of needle (cm^2)	0.0201 cm^2	
Supplied Sterile	Yes	
System Characteristics (Output Specs)		
Max Charge Density (µC / cm^2) per needle	67.16 @ 1 kΩ 8.01 @ 10 kΩ	
Max Average Power Density (W/ cm^2)	0.363 @ 1 kΩ 0.0516 @ 10 kΩ	
Net Charge (microcoulomb (µC) per pulse;	0 (Due to biphasic nature of the waveform)	
Where and how it is used	Low levels of electrical current are delivered by the external stimulator through electrodes placed percutaneously on the ear to target the associated cranial and occipital nerves.	
Anodes / Cathodes please identify the ground	The ground electrode of Drug Relief v1 is a single isolated wire separated from the assembly of signal wires, which creates a closed circuit for safe and proper functioning of the stimulation device.	

Identical to the predicate, the Drug Relief v1 device is intended to be a prescription (Rx) device for use by or on the order of a licensed healthcare practitioner. Both devices are body-worn, have identical indications for use and deliver electrical stimulation therapy as an aid in the reduction of opioid withdrawal symptoms. Both devices deliver biphasic electrical stimulation waveforms hence are charge balanced due to the a positive and negative phase between active electrode(s) and the ground electrode.

The *only difference* lies in the increase in shelf life from 6 to 12 months for the subject device compared to the predicate. This difference does not impact substantial equivalence in terms of safety and effectiveness of the Drug Relief v1 device as shown by sterilization validation and non-clinical performance testing.

VII. Performance Data

The nonclinical testing of Drug Relief v1 device included biocompatibility testing, electrical safety (electromagnetic compatibility and safety), performance bench testing and software validation.

The Drug Relief v1 device and its components are subjected to performance bench testing to validate the effectiveness of each unit. 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 v1 device. The Drug Relief v1 has equivalent performance specifications when compared to the predicate device.

The comparison bench testing information has been leveraged from information previously provided for the Drug Relief v1 device cleared under K211971 to establish substantial equivalence to the subject device, Drug Relief v1.

VIII. Conclusion

The results of the non-clinical tests have demonstrated that the Drug Relief v1 is as safe, as effective and performs as well as the legally marketed predicate device, and has no new intended use, thus rendering it substantially equivalent to the predicate device, Drug Relief v1 (K211971).