November 5, 2021

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

Re: K211971
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: October 5, 2021
Received: October 6, 2021

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,

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)*

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.

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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: K211971

1. SUBMITTER

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)
Classification : Class II
Product Code : PZR

III. PREDICATE DEVICE INFORMATION

Model Name : Drug Relief
Manufacturer : DyAnsys Inc.,
K Number : K173861
Classification Name : Percutaneous nerve stimulator for substance use disorders (21 CFR 882.5896)
Classification : Class II
Product Code : PZR

IV. DEVICE DESCRIPTION

The *Drug Relief v1* is designed to be used as an aid to reduce opioid withdrawal 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 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 and a duty cycle of 2 hours ON/1 minute OFF.

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 Drug Relief, the cited predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The DyAnsys, Inc *Drug Relief v1* device is substantially equivalent to its own legally marketed predicate device Drug Relief (K173861). It was evaluated through performance and non-clinical testing.

Table 6.1: Comparison of Technological Characteristics

MODEL NAME	Drug Relief (K173861)	Drug Relief v1 (Subject)	JUSTIFICATION ON SAFETY & EFFECTIVENESS VARIATIONS
MANUFACTURER	DyAnsys Inc	DyAnsys Inc	NA
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 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.	NA
PATIENT POPULATION	Adults	Adults	NA
TECHNOLOGICAL CHARACTERISTICS			

PULSE GENERATOR			
SHAPE	Rectangle	Rectangle	NA
PRODUCT DIMENSION (mm)	50 * 23 * 7	38 * 21 * 10	NA
MASS (g)	8 (including battery)	6 (including battery)	NA
PRODUCT SHAPE	Rectangle	Rectangle	NA
POWER			
FREQUENCY (HZ)	1 – 10 (Pulse with modulating frequency)	1 – 10 (Pulse with modulating frequency)	NA
WAVEFORM	Rectangular Pulse	Rectangle pulse	NA
ENERGY SOURCE	Battery Operated	Battery Operated	NA
BATTERY TYPE	P10 Zinc Air batteries	P13 Zinc Air batteries	Improved specification validated by electrical safety and bench testing.
BATTERY CAPACITY (mAh)	100	310	
NO. * VOLTAGE	3 * 1.4V	3 * 1.4 V	NA
PULSE WIDTH(ms)	0.980	0.980	NA
DUTY CYCLE	2 hours ON / 1 min OFF	2 hours ON / 1 min OFF	NA
BATTERY OPERATING TIME (hours)	120	120	NA
ENVIRONMENTAL			
OPERATING TEMPERATURE	5°C to 45°C	5°C to 45°C	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
SHEIF LIFE	6 months	6 months	NA

Table 13.3.2 Comparison of Technical System Characteristics

System Characteristic	Drug Relief (K173861)	Drug Relief v1 (Subject)
Pulse Generator		
Battery Type	Zinc Air Batteries, P10	Zinc Air Batteries, P13
Software Controlled	Yes	Yes
Mass (g)	6	8
Dimensions(mm)	50 * 23 * 7	38 * 21 * 10
Housing Material	ABS Plastic Material	ABS Plastic Material
Electrode Needle Arrays		
Introduction Method	Percutaneous	Percutaneous
Needle Material	Titanium	Titanium
Number of leads	4 (3 signal and 1 ground)	4 (3 signal and 1 ground)
Electrode Configuration	Single needle in all the 4 leads	Single needle in all the 4 leads
Needle Dimensions – Diameter (mm) x Length (mm)	0.4 x 2	0.4 x 2
Surface area of needle (cm^2)	0.0201	0.0201
System Characteristics (Output Specs)		
Max Charge Density (µC / cm^2)per needle	65.67 @ 1 kΩ 7.96 @ 10 kΩ	67.16 @ 1 kΩ 8.01 @ 10 kΩ
Max Average Power Density (W/ cm^2)	0.346 @ 1 kΩ 0.0509 @ 10 kΩ	0.363 @ 1 kΩ 0.0516 @ 10 kΩ
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.	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	The ground electrode of Drug Relief is a single isolated wire separated from the assembly of signal wires,	The ground electrode of Drug Relief v1 is a single isolated wire separated from the assembly of signal wires, which creates a

ground	which creates a closed circuit for safe and proper functioning of the stimulation device.	closed circuit for safe and proper functioning of the stimulation device.
Wire Assembly	4 units of wire with snap-fit ring where 3 nos constitute a single assembly for stimulation and the other one separate wire will act as a ground electrode.	4 units of wire with snap-fit ring where 3 nos constitute a single assembly for stimulation and the other one separate wire will act as a ground electrode.
Voltage Measurement Feasibility	A 3-pin connector is provided to measure the output voltage of the device once it is activated.	A 3-pin connector is provided to measure the output voltage of the device once it is activated.

Similar to Drug Relief, 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.

The two minor technological difference are 1) the inclusion of an advanced micro-controller to replace the older version and 2) upgrading the battery to a P13 zinc air battery. To accommodate the changes, the design of the PCB has been modified. These differences do not impact substantial equivalence in terms of safety and effectiveness of the Drug Relief v1 as shown by the electrical safety and non-clinical performance test reports.

The technical system characteristics and essential electrical safety parameters are identical or near identical as noted in Table 13.3.2. The minor technological differences do not impact the electrical safety parameters in a significant manner. Note that electrical safety parameters includes the actual electrical output delivered by the subject and predicate devices. The actual electrical output is near identical as mentioned in the technical sections of this submission hence the subsequent effectiveness remains equivalent to that of the predicate device.

VII. PERFORMANCE DATA

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

VIII. 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.

IX. CONCLUSION

Drug Relief v1 has been shown to be substantially equivalent to the identified predicate device based on identical device classification, intended use, indications for use statement, basic operating principles and near identical essential electrical safety parameters. The minor technological differences do not impact the electrical safety parameters and subsequent effectiveness of the device.

Hence it is concluded that by demonstrating the performance testing and with the indications for use, environment for use, compliance with the appropriate safety standards, the product Drug Relief v1 is substantially equivalent to the predicate device that was cleared by FDA - Drug Relief (K173861).