September 13, 2022

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

Re: K221425
Trade/Device Name: Primary Relief
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NHI
Dated: August 9, 2022
Received: August 11, 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,

Amber Ballard, PhD
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)*
K221425

Device Name
Primary Relief

Indications for Use *(Describe)*
The Primary Relief is a percutaneous electrical nerve stimulator (PENS) system indicated for up to 3 days for symptomatic relief of post-operative pain following cesarean section delivery or up to 3 days adjunctive symptomatic relief of post-operative pain following cardiac surgery.

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: K221425

I. SUBMITTER

Date Prepared: September 13, 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: Primary Relief
Classification Name: Percutaneous Electrical Nerve Stimulation (PENS) devices (21 CFR 882.5890)
Device Class: Class II
Product Code: NHI

III. PREDICATE DEVICE INFORMATION

Model Name: Primary Relief (K213188)
Manufacturer: DyAnsys, Inc.
Classification Name: Percutaneous Electrical Nerve Stimulation (PENS) devices (21 CFR 882.5890)
Device Class: Class II
Product Code: NHI

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

IV. DEVICE DESCRIPTION

The Primary Relief is designed to aid in the reduction of post-operative pain by the method of cranial electrical stimulation at the auricular stimulation points. The Primary Relief is a wearable, battery-operated device that is designed to administer periodical low level electrical pulses to the ear over three days / 72 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 72 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.

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 Primary Relief is a percutaneous electrical nerve stimulator (PENS) system indicated for up to 3 days for symptomatic relief of post-operative pain following cesarean section delivery or up to 3 days adjunctive symptomatic relief of post-operative pain following cardiac surgery..

The Indications for Use statement of Primary Relief is not identical to that of the predicate device; The only difference is the expansion in indications for use which is adequately supported through the clinical study results. The difference does not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use of symptomatic relief and management of pain through the delivery of short-term electrical stimulation.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The DyAnsys, Inc *Primary Relief* system is substantially equivalent to the legally marketed predicate device Primary Relief (K213188). It was evaluated through performance and non-clinical testing.

Table 6.1: Comparison of Technological Characteristics

MODEL NAME	**Primary Relief (Subject)**	**Primary Relief (K213188 - Predicate)**
MANUFACTURER	DyAnsys Inc.	DyAnsys Inc.
Intended Use / Indications for Use Statement		
INDICATIONS FOR USE	The Primary Relief is a percutaneous electrical nerve stimulator (PENS) system indicated for up to 3 days for symptomatic relief of post-operative pain following cesarean section delivery or up to 3 days adjunctive symptomatic relief of post-operative pain following cardiac surgery.	The Primary Relief is a percutaneous electrical nerve stimulator (PENS) system indicated for up to 3 days for symptomatic relief of post-operative pain following cesarean section delivery.
PATIENT POPULATION	Adults	Adults

SINGLE USE ELECTRODES	Yes	Yes
PORTABLE COMPONENTS	Yes	Yes

TECHNOLOGICAL CHARACTERISTICS		
PULSE GENERATOR		
PRODUCT DIMENSION (mm)	50 * 23 * 7	50 * 23 * 7
MASS (g)	8 g (including battery)	8 g (including battery)
PRODUCT SHAPE	Rectangle	Rectangle
POWER		
FREQUENCY (Hz)	1 – 100 (Sweep Pattern)	1 – 100 (Sweep Pattern)
WAVEFORM	Biphasic with Rectangular Pulse	Biphasic with Rectangular Pulse
BATTERY TYPE	P13 Zinc Air batteries that are non-rechargeable	P13 Zinc Air batteries
BATTERY CAPACITY	310 mAh	310 mAh
NO. x VOLTAGE (V)	3 x 1.4 V	3 x 1.4 V
PULSE WIDTH (ms)	~ 0.980	~ 0.980
DUTY CYCLE	Continuous Stimulation	Continuous Stimulation
TYPICAL BATTERY OPERATING TIME (hours)	72	72
ENVIRONMENTAL		
OPERATING TEMPERATURE	5 °C to 45 °C	Not publicly available
OPERATING HUMIDITY	40% to 80%	Not publicly available
ENVIRONMENT OF USE	Clinics, Hospital and Home environments	Clinics, Hospital and Home environments
STERILIZATION OF ELECTRODES	EtO Sterilization	EtO Sterilization
RE-USE	Single use Device	Single use Device
SHELF LIFE	6 months	6 months
ACCESSORIES	- Primary Relief with non activated batteries - Top Cover of Primary Relief - Sterile pack of needles for use with the Primary Relief device - Adhesive to fasten the needles - Adhesive for the Primary Relief device - Instructions for use	Not publicly available

Table 6.2: Comparison of System Characteristics

System Characteristic	Primary Relief (Subject)	Primary Relief (K213188 - Predicate)
PULSE GENERATOR		
Software Controlled	Yes	Yes
Mass (g)	8 g	8 g
Dimensions(mm)	50 * 23 * 7	50 * 23 * 7
Housing Material	ABS Plastic Material	ABS Plastic Material
ELECTRODE NEEDLE ARRAYS		
Introduction Method	Percutaneous	Percutaneous
Electrode Configuration	Single needle in all the 4 leads	Single needle in all the 4 leads
Tissue Contact	Skin/Tissue	Skin/Tissue
Electrode Type	Percutaneous fine needle	Percutaneous fine needle
Stimulating Electrode Material	Titanium	Titanium
Stimulating Electrode Shape	Straight	Straight
Number of leads	4 (3 signal and 1 ground)	4 (3 signal and 1 ground)
Needle Dimensions - Diameter (mm) x Length (mm)	0.4 x 2	0.4 x 2
Surface area of needle (cm^2)	0.0201 cm^2	0.0201 cm^2
Supplied Sterile	Yes	Yes
SYSTEM CHARACTERISTICS (OUTPUT SPECS)		
Net Charge (microcoulomb (µC) per pulse;	0 (Due to biphasic nature of the waveform)	Not publicly available
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 ground	The ground electrode of Primary Relief is a single isolated wire separated from the assembly of signal wires, which creates a closed circuit for safe and proper functioning of stimulation device.	The ground electrode of Primary Relief is a single isolated wire separated from the assembly of signal wires, which creates a closed circuit for safe and proper functioning of stimulation device.

The subject device, Primary Relief, has identical intended use, form factor, technological characteristics, mechanism of action and operating principles compared to that of the predicate device. Both devices are intended to be a prescription (Rx) devices for use by or on the order of a licensed healthcare practitioner. Both devices are body-worn, have similar indications for use and deliver electrical stimulation therapy for symptomatic relief and management of post-operative pain. 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 purpose of this submission is to expand the indications of use to include adjunctive use in patients with post- operative pain following cardiac surgery along with the already 510(k) cleared indication for post- operative pain following cesarean section delivery (K213188). The electrical stimulation parameters and the other characteristics remain identical to the predicate device.

The results from the clinical study (summarized below) have demonstrated the safety of the therapy and there were no serious adverse events observed during the study period.

VII. Performance Data

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

The Primary Relief device and its components are subjected to performance bench 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 72 hours to monitor the continuous performance. The pulse width, pulse duration, amplitude and current values are captured for the Primary Relief device. The Primary Relief has equivalent performance specifications when compared to the predicate device.

Clinical testing results presented with this submission have demonstrated the safety of the therapy. No serious adverse events were observed during the study.

VIII. Summary of Clinical Information

This was a single center, double arm, randomized, double-blinded prospective study involving 60 subjects who have undergone elective cardiac surgery and satisfied all the inclusion criteria. The subjects were split into the intervention group (29 patients; mean age = 53.86 ± 11.3 years) who received the Primary Relief device (Group A – treatment arm) and the control group (mean age = 54.90 ± 9.2 years) who received the sham device (Group B – identical to the subject device but delivers no stimulation and acts as placebo). The subject and sham devices were placed on the patients post-operatively prior to being awoken from anesthesia. Analgesics were administered upon patients' request to both treatment and control groups.

The primary efficacy endpoint is pain intensity at rest and on cough (measured through NRS – Numeric Rating Scale of 11 points with 0 signifying no pain and 10 being the worst pain imaginable) and the secondary efficacy endpoints included five measures intended to assess the pulmonary function. Post-operative baseline pain scores were obtained at 6-8 hours following placement of the subject and sham devices upon waking of the subjects from anesthesia. The primary and secondary endpoints were measured according to validated and widely used tools at 9 intervals spanning 72 hours.

The analysis showed that minimally invasive percutaneous electrical nerve stimulation treatment using Primary Relief device reduces the pain score compared to that of the control group :

- On average, the Group A score was 1.19 units (SE=0.16; P-value < 0.001) less than the control group (Group B), for the group-wise change in pain score at rest.
- On average, the Group A score was 1.25 units (SE=0.23; P-value < 0.001) less than the control group (Group B), for the group-wise change in the pain score during cough.

The effect was maintained throughout the study period and during rest and cough situations.

No complications or adverse events were observed in any of the subjects during the study period across both arms.

IX. Conclusion

Primary Relief system has been shown to be substantially equivalent to the identified predicate device based on comparison of device classification, intended use, indications for use statement and basic operating principle. Clinical and non-clinical testing shows the suitability of Primary Relief for its intended use of relieving post-operative pain following C-section delivery and for adjunctive use following cardiac surgery.