January 31, 2022

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

Re: K213188
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: December 25, 2021
Received: December 27, 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,

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)*
K213188

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 .

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: K213188

I. SUBMITTER

Date Prepared: January 31, 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: SPRINT PNS System (K202660)
Manufacturer: SPR Therapeutics, Inc.
Classification Name: Percutaneous Electrical Nerve Stimulation (PENS) devices
(21 CFR 882.5890)
Device Class: Class II
Product Code: NHI

Drug Relief (K173861) manufactured by our company has been used as reference device in this submission.

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 3 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.

The Indications for Use statement of Primary Relief is not identical to that of the predicate device; however, the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The DyAnsys, Inc *Primary Relief* system is substantially equivalent to the legally marketed predicate device SPRINT PNS System (K202660). It was evaluated through performance and non-clinical testing.

Table 6.1: Comparison of Technological Characteristics

MODEL NAME	**Primary Relief (Subject)**	**SPRINT PNS System (K202660 - Predicate)**	**Drug Relief (K173861 - Reference)**
MANUFAC-TURER	DyAnsys Inc.	SPR Therapeutics	DyAnsys Inc.
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.	The SPRINT Peripheral Nerve Stimulation (PNS) System is indicated for up to 60 days in the back and/ or extremities for: • Symptomatic relief of chronic, intractable pain, post surgical and post-traumatic acute pain; • Symptomatic relief of post-traumatic pain; • Symptomatic relief of post-operative pain.	The Drug Relief is a percutaneous nerve field stimulator 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	UNK	Adults
SINGLE USE ELECTRODES	Yes	UNK	UNK
PORTABLE COMPONENTS	Yes	UNK	UNK
TECHNOLOGICAL CHARACTERISTICS			
PULSE GENERATOR			
PRODUCT DIMENSION (mm)	50 * 23 * 7	UNK	50 * 23 * 7
MASS (g)	8 (including battery)	UNK	6 (including battery)
PRODUCT SHAPE	Rectangle	UNK	Rectangle
POWER			
FREQUENCY (Hz)	1 - 100 (Sweep Pattern)	UNK	1 - 10
WAVEFORM	Biphasic with Rectangular Pulse	UNK	Rectangular Pulse
BATTERY TYPE	P13 Zinc Air batteries	UNK	P10 Zinc Air batteries

BATTERY CAPACITY (mAh)	310	UNK	100
NO. x VOLTAGE (V)	3 x 1.4 V	UNK	3 x 1.4 V
PULSE WIDTH(ms)	~ 0.980	UNK	~ 0.980
DUTY CYCLE	Continuous (0 hrs OFF)	UNK	2 hours ON / 1 min OFF
TYPICAL BATTERY OPERATING TIME (hours)	72	–UNK	120
ENVIRONMENTAL			
ENVIRONMENT OF USE	Clinics, Hospital and Home environments	UNK	Clinics, Hospital and Home environments
STERILIZATION OF ELECTRODES	EtO Sterilization	UNK	EtO Sterilization
RE-USE	Single use Device	UNK	Single use Device
SHELF LIFE	6 months	24 months	6 months
UNK = Not able to determine from publicly available documents. * = Duty Cycle is mentioned as a percentage in the cleared 510(k) summary of predicate device.			

Table 6.2: Comparison of System Characteristics

System Characteristic	Primary Relief (Subject)	SPRINT PNS System (K202660 - Predicate)	Drug Relief (K173861 - Reference)
Pulse Generator			
Software Controlled	Yes	UNK	Yes
Housing Material	ABS Plastic Material	UNK	UNK
Electrode Needle Arrays			
Introduction Method	Percutaneous	UNK	UNK
Tissue Contact	Skin/Tissue	UNK	UNK
Electrode Type	Percutaneous fine needle	UNK	UNK
Stimulating Electrode Material	Titanium	UNK	Titanium

Stimulating electrode shape	Straight	UNK	UNK
Electrode Configuration	Single needle in all the 4 leads	UNK	Single needle in all the 4 leads
Number of leads	4 (3 signal and 1 ground)	UNK	4 (3 signal and 1 ground)
Diameter of percutaneous extension (mm)	0.4	UNK	0.4
Electrode Length (mm)	2	UNK	2
Surface area of needle (cm^2)	0.0201 cm^2	UNK	0.0201 cm^2
Supplied Sterile	Yes	UNK	UNK

Similar to SPRINT PNS system and Drug Relief, the Primary Relief device is intended to be a prescription (Rx) device for use by or on the order of a licensed healthcare practitioner. All the three devices are body-worn and deliver electrical stimulation therapy for symptomatic relief and management of pain.

The first minor technological difference lies in the placement of electrodes and the electrode configuration. The flexible SPRINT PNS percutaneous stimulation electrode passes through the skin to a target peripheral nerve associated with a painful area, either in the back or extremities. In contrast, the Primary Relief stimulation electrodes pass through the skin to a depth of 2 mm on the ear to target the associated cranial and occipital nerves of the pain region. The ground electrode of SPRINT PNS is placed transcutaneously whereas that of Primary Relief is placed percutaneously similar to the stimulation electrodes. These differences do not raise any new questions on safety and effectiveness, as both designs pass through the skin and stay in place for the appropriate treatment period, and safely deliver electrical stimulation for the desired short-term period. The clinical study results along with the identical design present in the Drug Relief device show that the device is safe to use on patients for pain management.

The second minor difference is in the duration of patient contact where the SPRINT PNS system is applied for up to 60 days whereas that of the Primary Relief system is up to 3 days. This difference does not raise any new questions on safety and effectiveness.

Results from the clinical study have demonstrated the safety of the therapy and there were no serious adverse events observed during the study and the follow-up period.

Along with results from clinical study, performance bench testing has been performed to establish substantial equivalence of Primary Relief to the cited predicate device. The reference device has been utilized in comparison bench testing to denote the equivalent output characteristics. Hence, evaluation of the effect of the technological differences supports the finding of substantial equivalence.

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 reference 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 Drug Relief device. The Primary Relief has equivalent performance specifications when compared to the predicate and reference devices.

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 centre, double arm, randomized, controlled, parallel assignment prospective study involving 44 participants who underwent Cesarean section (C-section) delivery. The subjects were split into the intervention group (mean age = 24.7 ± 2.6 years) who received the Primary Relief device as the primary method of analgesia and the control group (mean age = 26.6 ± 3.9 years) who received standard analgesics for management of post-operative pain.

The primary efficacy endpoint is pain intensity and the secondary efficacy endpoints included six measures intended to assess the quality of life. The Participants were asked to rate the primary and secondary endpoints on the validated and widely used Numerical Rating Scale (NRS) at 23 intervals spanning 72 hours.

The analysis showed that minimally invasive nerve stimulation intervention using Primary Relief device reduces the pain score faster than the standard control treatment. A very high least-square means difference post six hours suggests that the intervention treatment is clearly more effective in reducing the pain score compared to the treatment received by the control arm (p-value < 0.001). Further analysis on the secondary endpoints also showed a significant positive response in the device intervention group (p -value < 0.04) compared to the control group.

No complications or adverse events were observed in any of the participants during the study period across the two 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.