December 20, 2021

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

Re: K212859
Trade/Device Name: First 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 26, 2021
Received: September 8, 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,

for Amber Ballard, PhD
Assistant Director, Neurodegenerative Devices Team
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)*
K212859

Device Name
First Relief

Indications for Use *(Describe)*
The First Relief is a percutaneous electrical nerve stimulator (PENS) system indicated for multiple treatments up to 56 days for symptomatic relief of chronic, intractable pain from diabetic peripheral neuropathy.

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: K212859

I. SUBMITTER

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

II. DEVICE INFORMATION

Trade Name: First Relief
Classification Name: Percutaneous Electrical Nerve Stimulation (PENS) devices (21 CFR 882.5890)
Device Class: Class II
Product Code: NHI

III. PREDICATE DEVICE

Model Name: SPRINT PNS System (K202660, K181422, K170902, K161154)
Manufacturer: SPR Therapeutics, Inc.

First Relief v1 (K202940) manufactured by our company has been used as reference device in this submission.

Both the predicate and reference devices have not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The First Relief is designed to aid in the treatment of chronic pain symptoms by the method of cranial electrical stimulation at the auricular stimulation points. The First Relief is a wearable, battery-operated device that is designed to administer periodical low level electrical pulses to the ear over seven days / 168 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 168 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 First Relief is a percutaneous electrical nerve stimulator (PENS) system indicated for multiple treatments up to 56 days for symptomatic relief of chronic, intractable pain from diabetic peripheral neuropathy.

The Indications for Use statement of First 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. 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 *First 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	**First Relief (Subject)**	**SPRINT PNS System (K202660 - Predicate)**	**First Relief v1 (K202940 - Reference)**
MANUFACTURER	DyAnsys Inc.	SPR Therapeutics	DyAnsys Inc.
Intended Use / Indications for Use Statement			
INTENDED USE	Short-term electrical stimulation is delivered for symptomatic relief and management of pain	Short-term electrical stimulation is delivered for symptomatic relief and management of pain	Short-term electrical stimulation is delivered for symptomatic relief and management of pain
INDICATIONS FOR USE		The SPRINT Peripheral Nerve Stimulation (PNS) System is	The First Relief v1 is a percutaneous electrical nerve field stimulator (PENFS) system intended to be used in patients 11-18 years of

	The First Relief is a percutaneous electrical nerve stimulator (PENS) system indicated for multiple treatments up to 56 days for symptomatic relief of chronic, intractable pain from diabetic peripheral neuropathy.	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.	age with functional abdominal pain associated with irritable bowel syndrome (IBS). The First Relief v1 is intended to be used for 120 hours per week up to 3 consecutive weeks, through application to Cranial Nerves V, VII, IX and X, and the occipital nerves identified by trans-illumination, as an aid in the reduction of pain when combined with other therapies for IBS.
PATIENT POPULATION	Adults	Adults	Children
SINGLE USE ELECTRODES	Yes	Yes	Yes
PORTABLE COMPONENTS	Yes	Yes	Yes
DURATION OF PATIENT CONTACT (days)	7 days	60 days	5 days
NUMBER OF TREATMENTS	8 times	Once	3 times
MAXIMUM TOTAL DURATION OF THERAPY (days)	7 x 8 = 56 days*	60 x 1 = 60 days	5 x 3 = 15 days
*** Note that the First Relief device is applied for 168 hours per week on alternative weeks for 16 consecutive weeks resulting in 56 days / 8 weeks of treatment and 49 days / 7 weeks of no device in between.**			
TECHNOLOGICAL CHARACTERISTICS			
PULSE GENERATOR			
PRODUCT DIMENSION (mm)	50 * 23 * 7	62 * 37 * 14	50 * 23 * 7
MASS (g)	5 (including battery)	24	5 (including battery)
PRODUCT SHAPE	Rectangle	Rectangle	Rectangle
POWER			
FREQUENCY (Hz)	1 – 10 (Sweep Pattern)	5 - 100	1 - 10

WAVEFORM	Biphasic with Rectangular Pulse	Biphasic with Rectangular Pulse	Biphasic with Rectangular Pulse
BATTERY TYPE	P10 Zinc Air batteries that are non-rechargeable	Rechargeable Lithium Ion Polymer cell	P10 Zinc Air batteries that are non-rechargeable
BATTERY CAPACITY (mAh)	100	240	100
NO. x VOLTAGE (V)	3 x 1.4 V	1 x UNK	3 x 1.4 V
PULSE WIDTH(ms)	1	0.2	~ 1
DUTY CYCLE	2 hours ON / 2 hours OFF	50 % or 100 % *	2 hours ON / 2 hours OFF
TYPICAL BATTERY OPERATING TIME (hours)	168	12 - 24	120
ENVIRONMENTAL			
OPERATING TEMPERATURE	5 °C to 45 °C	5 °C to 40 °C	5 °C to 45 °C
OPERATING HUMIDITY	40% to 80%	15% to 90%	40% to 80%
ENVIRONMENT OF USE	Clinics, Hospital and Home environments	Clinics, Hospital and Home environments	Clinics, Hospital and Home environments
STERILIZATION OF ELECTRODES	EtO Sterilization	EtO Sterilization	EtO Sterilization
RE-USE	Single use Device	Single use Device	Single use Device
SHELF LIFE	6 months	24 months	6 months
ACCESSORIES	- First Relief with non activated batteries - Top Cover of First Relief - Sterile pack of needles for use with the First Relief device - Adhesive to fasten the needles - Adhesive for the First Relief device - Instruction for use	- OnePass Introducer - MicroLead - Pulse Generator - Hand-Held Remote - Recharging base with power supply - Mounting pad adhesive - Connectors and Adapter - Adhesive Bandage - Instructions for use	- First Relief v1 with non activated batteries - Top Cover of First Relief v1 - Sterile pack of needles for use with First Relief v1 - Adhesive to fasten the needles - Adhesive for the First Relief v1 device - Instruction for use
UNK = Not able to determine from publicly available documents. FDA may have access in cleared 510(k). * = Duty Cycle is mentioned as a percentage in the cleared 510(k) summary of predicate device.			

Table 6.2: Comparison of System Characteristics

System	First Relief	SPRINT PNS System	First Relief v1

Characteristic	(Subject)	(K202660 - Predicate)	(K202940 - Reference)
Pulse Generator			
Software Controlled	Yes	Yes	Yes
Weight (g)	5 g	24 g	5 g
Dimensions(mm)	50 * 23 * 7 mm	62 * 37 * 14	50 * 23 * 7 mm
Housing Material	ABS Plastic Material	UNK	ABS Plastic Material
Electrode Needle Arrays			
Introduction Method	Percutaneous	Percutaneous	Percutaneous
Tissue Contact	Skin/Tissue	Skin/Tissue	Skin/Tissue
Electrode Type	Percutaneous fine needle	Percutaneous fine wire	Percutaneous fine needle
Stimulating Electrode Material	Titanium	316L Stainless Steel	Titanium
Stimulating electrode shape	Straight	Straight with tine	Straight
Electrode Configuration	Single needle in all the 4 leads	1 pair (1 percutaneous electrode and 1 surface electrode)	Single needle in all the 4 leads
Number of leads	4 (3 signal and 1 ground)	1	4 (3 signal and 1 ground)
Diameter of percutaneous extension (mm)	0.4	0.64	0.4
Electrode Length (mm)	2	15.2	2
Surface area of needle (cm²)	0.0201 cm²	UNK	0.0201 cm²
Supplied Sterile	Yes	Yes	Yes
System Characteristics (Output Specs)			
Pulse Duration (ms)	1	0.2	1
Net Charge (µC / pulse)	0 (due to the nature of the biphasic waveform)	0	0
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	Low levels of electrical current are delivered by the external stimulator through electrodes placed percutaneously	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.	in proximity to a target peripheral nerve associated with a painful area.	target the associated cranial and occipital nerves.
Anodes / Cathodes please identify the ground	The ground electrode of First Relief 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.	The ground electrode of SmartPatch PNS is the surface electrode in contact with the patient's skin, which creates a closed circuit for safe and proper functioning of the stimulation device whereas the active electrode is placed near the target nerve.	The ground electrode of First 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.

Similar to SPRINT PNS system and First Relief v1, the First 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. All the three 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 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 depth of 2-4 cm, to a target peripheral nerve associated with a painful area, either in the lower back or extremities. In contrast, the First 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 First 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 First Relief v1 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 First Relief system is 7 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 First 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 First Relief device included biocompatibility testing, electrical safety (electromagnetic compatibility and safety), performance bench testing and software validation.

The First 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 168 hours to monitor the continuous performance. The pulse width, pulse duration, amplitude and current values are captured for the First Relief device. The First 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 as well as the subsequent follow-up period.

VIII. Summary of Clinical Information

This was a single centre, three arm, randomized, controlled, parallel assignment, double blinded, prospective study involving 63 patients (30 – 74 years old; mean age = 57.0 ± 9.1 years) with Type II diabetes established as per American Diabetes Association (ADA guidelines) along with a diagnosis of diabetic peripheral neuropathy made after a careful clinical examination. The inclusion criteria included being 18 to 75 years of age, known diabetes mellitus (KDM) for a duration of minimum of 5 years, and has diabetic neuropathic pain based on Toronto Expert Panel on diabetic neuropathy diagnostic criteria.

Patients in two out of the three arms received the First Relief (Group A - first treatment arm) and sham device (Group C - identical to the subject device but delivers no stimulation and acts as placebo). A third arm included the use of an already cleared FDA device (Group B - 1 Hz stimulation frequency) as the second treatment arm. The devices (treatment and sham) were applied on a bi-weekly basis for 16 weeks and the subjects visited every week either for treatment or follow-up/removal of the device.

The primary efficacy endpoint is pain intensity measured through Visual Analog Scale (VAS) score and the secondary efficacy endpoints are vibration perception threshold (VPT) value, insomnia severity index (ISI), overall neuropathy limitations scale (ONLS), Hamilton rating scale for anxiety – A (HAM-A). The five endpoints were measured weekly over the study period of 16 weeks. A 30-day and 90-day follow-up was also part of the study design to understand the long-term impact of the treatment.

The VAS pain score analysis showed a significant reduction in the pain score in Group B from the start of the treatment to the end. This improvement persisted throughout the 90-day follow-up, suggesting that the treatment was a long term improvement in neuropathic pain and not a short term improvement. Both the treatments showed a marked improvement (3.12 and 3.15 against 1.18 for the control group).

The secondary outcome measures (VPT, Insomnia, ONLS and HAM) also showed similar improvements to the pain score, showing significant improvement in sleep and mood as the neuropathic pain decreased.

However, treatment B (First Relief device) was the more effective one at reducing the ONLS and HAM scores over the long term.

The post hoc analysis of ONLS scores indicates a significant difference in the reduction of ONLS score in group B compared to group C (Adj. P-value = 0.007). By contrast, the Adj P-value is <0.066 for comparison between A to C for 90-days of follow up.

Similarly, the post hoc analysis of HAM scores indicates a significant difference in the reduction of HAM score in group B compared to group C (Adj. P-value <0.001). In comparison, Adj. P-value is <0.105 for comparison between A to C for 90-days of follow up.

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

IX. Conclusion

First 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 First Relief for its intended use.