December 29, 2020

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

Re: K202940
Trade/Device Name: First Relief v1
Regulation Number: 21 CFR 876.5340
Regulation Name: Non-implanted nerve stimulator for functional abdominal pain relief
Regulatory Class: Class II
Product Code: QHH
Dated: July 5, 2020
Received: September 30, 2020

Dear Mr. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name

First Relief v1

Indications for Use *(Describe)*

The First Relief v1 is a percutaneous electrical nerve field stimulator (PENFS) system intended to be used in patients 11-18 years of 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.

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.

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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: K202940

1. Applicant Information:

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

Device Information

Classification :Class II
Trade Name :First Relief v1
Classification Name :Non-Implanted Nerve Stimulator For Pain Associated With Irritable Bowel Syndrome
Product Code :QHH

2. Predicate Device:

DEN Number: DEN180057
Model Name: IB - Stim
Manufacturer: Innovative Health Solutions.Inc.,

3. Device Description:

The First Relief v1 is designed to aid in the reduction of pain when combined with other therapies of IBS in patients 11 – 18 years of age with Functional Abdominal Pain associated with the Irritable bowel syndrome (IBS) by the method of Cranial electrical stimulation at the auricular stimulation points. The First 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 (V, VII, IX and X) on the ear through a set of wire assembly and Stimulation needles. Three zinc air batteries with 1.4 V each provides the required stimulation energy for a maximum of 120 hours. There are three Stimulation electrodes 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

4. Intended Use:

The First Relief v1 is a Percutaneous Electric Nerve Field Stimulator (PENFS) system intended to be used in patients 11 -18 years of 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 branches of cranial nerves V, VII, IX and X and the occipital nerves identified by transillumination as an aid in the reduction of pain when combined with other therapies for IBS.

5. Comparison to Predicate Device:

The DyAnsys .Inc., First Relief v1 is substantially equivalent to legally marketed predicate device IB-Stim (DEN180057). It was evaluated through Non-Clinical testing.

MODEL NAME	**Drug Relief (K173841)**	**First Relief v1 (Subject)**	**IB-Stim (DEN180057)**
MANUFACTURER	DyAnsys .Inc.,	DyAnsys .Inc.,	Innovative Health Solutions. Inc.,
INTENDED 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, VI, IX and X, and the occipital nerves identified by transillumination.	The First Relief v1 is a Percutaneous Electrical Nerve Field Stimulator (PENFS) system intended to be used in patients 11-18 years of age with functional abdominal pain associated with the 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 branches of Cranial nerves V, VI, IX and X the occipital nerves identified by transillumination as an aid in the reduction of pain when combined with other therapies for IBS.	The IB-Stim is a percutaneous Electrical Nerve Field Stimulator (PENFS) system intended to be used in patients 11-18 years of age with functional abdominal pain associated with the irritable bowel syndrome (IBS). The IB-Stim is intended to be used for 120 hours per week up to 3 consecutive weeks, through application to branches of Cranial Nerves V, VI, IX and X and the occipital nerves identified by transillumination as an aid in the reduction of pain when combined with other therapies for IBS.
PATIENT POPULATION	Adults	Child	Child
TECHNOLOGICAL CHARACTERISTICS			
SHAPE	Rectangle	Rectangle	Rectangle
PRODUCT DIMENSION, mm	50*23*7 mm	50*23*7 mm	36*16*7 mm
WEIGHT, Kg	6 gm (including battery)	6 gm (including battery)	5 gm
NEEDLE DIMENSIONS, mm	0.4*2 mm (width*length)	0.4*2 mm (width*length)	0.5*2 mm (width*length)
Wire Assembly	4 units of wire with snap-fit ring , where 3 nos constitute a	4 units of wire with snap-fit ring , where 3 nos constitute a single	Four stainless steel wire with four stimulation needles each. There are 3

	single assembly for stimulation and the other one separate wire will act as a ground electrode.	assembly for stimulation and the other one separate wire will act as a ground electrode.	stimulation wires with 4 array of needle each and 1 ground wire with 1 needle.
WIRE ASSEMBLY TYPE	Wire assembly without stimulation needles is soldered with the pulse generator	Wire assembly without stimulation needles is soldered with the pulse generator	Wire assembly is connected with the stimulation needles at one end and has the facility to connect with the pulse generator. It is sterilized and packed separately.
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	Not Feasible
POWER:			
FREQUENCY	1 Hz to 10 Hz	1 Hz to 10 Hz	1 Hz to 10 Hz
DUTY CYCLE	2 Hours ON/1 minute OFF	2 Hours ON/2 Hours OFF	2 Hours ON/2 Hours Off
OPERATING TIME, HOURS	120 hours (5 days)	120 hours (5 days)	120 hours (5 days)
WAVEFORM	Rectangle pulse	Rectangle Pulse	Rectangle Pulse
(ENERGY SOURCE) BATTERY OPERATION	Yes	Yes	Yes
BATTERY TYPE	Zinc Air, Battery P10	Zinc Air Battery P10	Lithium ion battery, CR1225
BATTERY CAPACITY	100 mAh	100 mAh	50 mAh
VOLTAGE	3*1.4V	3*1.4V	1*3V
PULSE WIDTH	0.980 ms	0.980 ms	0.980 ms
ENVIRONMENT			
OPERATING TEMPERATURE	5 °C to 45 °C	5 °C to 45 °C	5 °C to 45 °C
OPERATING HUMIDITY	40% to 80%	40% to 80%	20% to 80%
ENVIRONMENT OF USE	Clinics, Hospital, Home environments	Clinics, Hospital, Home environments	Clinics, Hospital, Home environments
STERILIZAITON	EtO Sterilization	EtO Sterilization	Irradiation (Gamma)
RE-USE	Single Use device	Single Use Device	Single Use Device
SHElF LIFE	6 Months	6 Months	12 Months
PACKAGE	The drug relief device and its accessories are packed in a blister. This is then placed in a carton box. Each carton box has five device	The First Relief v1 device and its accessories are packed in a blister. This is then placed in a carton box Each carton box has multiple devices	The IB-Stim and its accessories packed in a blister
ACCESSORIES	-Drug Relief with the non activated batteries - Cover of the Drug Relief - Sterile pack of needles for use with the Drug Relief - Adhesive to fasten the needles	First Relief v1 with the non activated batteries - Cover of the First Relief v1 - Sterile pack of needles for use with the First Relief v1 - Adhesive to fasten the needles	- The IB-Stim device with inserted batteries - Cover of the IB-Stim - Sterile pack of Needles for use with the IB-Stim - Tegaderm has been used to fasten

	- Adhesive for the Drug Relief device - Instruction for use	- Adhesive for the First Relief v1 device - Instruction for use	the device - Alcohol Swab -Instruction for use
PLANNING & PURCHASE			
WARRANTY	NA	NA	NA

Difference Between the Legally Marketed Predicate Device:

- Difference in Components

1. The energy source (battery) has been replaced with higher capacity for more effective treatment
2. Device adhesive has been replaced with a biocompatible, stretchable adhesive exclusively used for wearables and the EtO sterilization has been made used for needles.

These differences does not affect the safety and effectiveness of the device.

6. Performance Testing Summary

The First 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, pulse duration, amplitude and current values are captured for the First Relief v1 device. The First Relief v1 has equivalent Performance specifications when compared to the predicate device.

The form factors, material for sterilization and some patient contacting materials of the First Relief v1 are similar to the 510(K) cleared device Drug Relief (K173861).

7. Compliance with Standards

The First Relief v1 complies with the following standards

1. IEC 60601-1
2. IEC 60601-1-2
3. ISO 10993-1
4. ISO 10993-5
5. ISO 10993-6
6. ISO 10993-7
7. ISO 10993-10
8. ISO 10993-11
9. ISO 11135

8. 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.

9. Non-Clinical Testing Summary

The bench test has been performed and found that the First Relief v1 met all the requirements specifications and standards requirements. The testings includes the following:

1. MEE testing as per IEC 60601-1
2. EMI/EMC testing as per IEC 60601-1-2
3. Biocompatibility testing as per ISO 10993
4. Performance testing

10.Conclusion

Hence it is concluded that by demonstrating the Performance testing and with the Indications For Use, Environment for Use, Biocompatibility and compliance with the same harmonized standards, the product First Relief v1 is substantially equivalent to the predicate device **IB-Stim** (DEN180057) that was cleared by FDA.