August 14, 2020

Micron Medical Corporation
Elizabeth Greene
Chief Compliance Officer
606 Banyan Trail
Boca Raton, Florida 33431

Re: K200848
Trade/Device Name: Stimulator, Stimulator Kit, External Transmitter, External Transmitter Kit
Regulation Number: 21 CFR 882.5870
Regulation Name: Implanted peripheral nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZF
Dated: May 15, 2020
Received: May 19, 2020

Dear Elizabeth Greene:

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,

Vivek Pinto, PhD
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)*

K200848

Device Name
Moventis PNS

Indications for Use *(Describe)*

Moventis PNS is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. The Moventis PNS is not intended to treat pain in the craniofacial region.

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

for

Moventis PNS

1. Submission Sponsor

Micron Medical Corporation
Address: 606 Banyan Trail
Boca Raton
Florida, 33431
USA
Phone/Fax: 888.691.0585
Contact: Elizabeth Greene, Chief Compliance Officer

2. Date Prepared

March 30, 2020

3. Device Identification

Trade/Proprietary Name:	Moventis PNS
Common/Usual Name:	Peripheral Nerve Stimulator
Classification Name:	Stimulator, Peripheral Nerve, Implanted (Pain Relief)
Classification Regulation:	882.5870
Product Code:	GZF
Device Class:	Class II
Classification Panel:	Neurology

4. Legally Marketed Predicate Device(s)

K141399	Freedom SCS System	FRE4-A000
K171366	StimQ PNS System	STQ4, PDBT-915-2A

5. Device Description

Moventis PNS™ is used for peripheral nerve stimulation to provide therapeutic relief for chronic, intractable pain originating from peripheral nerves. The therapy utilizes pulsed electrical waveforms to create an electrical energy field that acts on afflicted peripheral nerves to alter the transmission of pain signals from those nerves to the brain. Moventis PNS is comprised of percutaneous Implanted Pulse Generator (pIPG) and a pre-programmed External Transmitter (ETx) worn outside the body over the general area of the pIPG to provide signal and power.

pIPG Kits

Moventis PNS has three (3) pIPG Kits consisting of the following components.

pIPG(s)	Percutaneous implanted pulse generator comprised of an embedded receiver, flexible integrated circuit board, encased by polyurethane (Pellethane 55D) tubing and tines with four (4) electrodes (Platinum Iridium 90:10). pIPG electrodes are placed next to peripheral nerves.
Stylet	Curved stainless-steel wire with a polypropylene handle inserted into pIPG to provide rigidity during implantation.
Introducers	Stainless steel dilator and yellow Hytrel introducer assembly used to create a pathway for placement of pIPG next to peripheral nerves.

ETx Kit

Moventis PNS has one (1) External Transmitter Kit consisting of the following:

ETx	External Transmitter (ETx) housing includes the following components: A. Microwave Field Stimulator (MFS) – A printed circuit board (PCB) that generates RF power with embedded waveform parameter setting; B. Switch Membrane – An elastomeric silicon rubber pad that corresponds to switches on the MFS that allows the user to turn the device on/off or increase or decrease power amplitude, or select program; C. Battery Assembly – Battery and wire assembly for charging and MFS power delivery. D. Transmitting Antenna – Antenna and coaxial cable assembly that is attached to the ETx used to transmit energy to pIPG.
Battery Charger	Off-the-shelf battery charger that uses a power adapter micro-USB cable.

6. Indication for Use Statement

Moventis PNS is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. Moventis PNS is not intended to treat pain in the craniofacial region.

7. Substantial Equivalence Discussion

The following table compares Moventis PNS to the predicate devices with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A. Comparison of the technological characteristics of Moventis PNS to predicate devices.

Comparator	New Device	Predicate Device (Primary)	Predicate Device
Device Name	Moventis PNS	StimQ PNS System	Freedom SCS System
Regulatory Decision	K200848	K171366	K141399
Product Code	GZF	Same as Moventis	GZB
Regulation No.	882.5870	Same as Moventis	882.5880
Regulation Name	Stimulator, Peripheral Nerve, Implanted (Pain Relief)	Same as Moventis	Stimulator, Spinal-Cord, Implanted (Pain Relief)

Comparator	New Device	Predicate Device (Primary)	Predicate Device
Intended Use	Stimulation of peripheral nerves for chronic, intractable pain of peripheral nerve origin	Same as Moventis	Stimulation of spinal nerves for chronic, intractable pain of trunk and lower limbs
Mode of Action	RF wireless transmission of energy to produce stimulation. ETx sends pulsed RF signal on carrier frequency (915MHz) to pIPG.	RF wireless transmission of energy to produce stimulation. SWAG sends pulsed RF signal on carrier frequency (915MHz) to Stimulator.	Same as Moventis
Implant Site	Peripheral nerves, excluding craniofacial region	Same as Moventis	Epidural space, L5 to T5
Environmental Use	Hospital, Home	Same as Moventis	Same as Moventis
Intended Clinician	Orthopedic, Neurosurgeon, Anesthesiologist	Same as Moventis	Same as Moventis
Intended User	Layperson	Same as Moventis	Same as Moventis
Electrode Material	Platinum-iridium 90:10	Same as Moventis	Same as Moventis
pIPG Body Material	Polyurethane 2363-55D	Same as Moventis	Same as Moventis
pIPG Length	45 cm	Same as Moventis	Same as Moventis
pIPG Diameter	1.35 mm	Same as Moventis	Same as Moventis
Electrode Array Length	24.0 mm	24.0 mm (FR4A/SRAY)	Same as Moventis
No. of Electrodes	4	4 (FR4A/SRAY)	Same as Moventis
Electrode Length	3.0 millimeters	Same as Moventis	Same as Moventis
Electrode Spacing	4.0 mm	Same as Moventis	Same as Moventis
Electrode Surface Area	12.72 mm^2	Same as Moventis	Same as Moventis
Method of Introduction	Percutaneous	Same as Moventis	Same as Moventis
Tissue Contact	Yes	Same as Moventis	Same as Moventis
Sterilization	Ethylene Oxide (EO)	Same as Moventis	Same as Moventis
Labeling	Sterile, Single Use, Prescription Use	Same as Moventis	Same as Moventis
Pulse Frequency	5 to 1,500 Hz	Same as Moventis	Same as Moventis
Pulse Width	50 to 500 µsec	Same as Moventis	Same as Moventis
Polarity	Fixed	Programmable	Same as Moventis
Waveform	Charge Balanced (delayed) Biphasic asymmetrical	Same as Moventis	Same as Moventis
Pulse Shape	Decaying Exponential	Same as Moventis	Same as Moventis
Current/Voltage Regulated	Current	Same as Moventis	Same as Moventis
Output Voltage (300 Ω)	0 to 7.0 V	0 to 4.1 V	0 to 6.3 V
Output Voltage (500 Ω)	0 to 8.3 V	0 to 6.4 V	0 to 7.2 V
Output Voltage (800 Ω)	0 to 9.4 V	0 to 7.5 V	0 to 8.0 V
Output Current (300 Ω)	0 to 23.3 mA	0 to 13.5 mA	0 to 21.0 mA
Output Current (500 Ω)	0 to 16.6 mA	0 to 12.8 mA	0 to 15.0 mA
Output Current (800 Ω)	0 to 11.7 mA	0 to 9.4 mA	0 to 10.0 mA
Avg. Cur. Density* (300Ω)	139.5 mA/cm^2	105.0 mA/cm^2	111.6 mA/cm^2
Avg. Cur. Density* (500Ω)	100.2 mA/cm^2	95.1 mA/cm^2	96.7 mA/cm^2
Avg. Cur. Density* (800Ω)	68.5 mA/cm^2	69.0 mA/cm^2	77.0 mA/cm^2
Max. Phase Charge* (300Ω)	2.9 µC/pulse	6.8 µC/pulse	10.5 µC/pulse
Max. Phase Charge* (500Ω)	2.9 µC/pulse	6.4 µC/pulse	7.2 µC/pulse
Max. Phase Charge* (800Ω)	2.9 µC/pulse	4.7 µC/pulse	5.0 µC/pulse
Max. Charge Density* (300Ω)	23.2 $µC/cm^2$	53.1 $µC/cm^2$	82.5 $µC/cm^2$
Max. Charge Density* (500Ω)	23.2 $µC/cm^2$	50.3 $µC/cm^2$	56.6 $µC/cm^2$
Max. Charge Density* (800Ω)	22.6 $µC/cm^2$	36.9 $µC/cm^2$	39.3 $µC/cm^2$
Max. Cur. Density* (300Ω)	183.3 mA/cm^2	106.1 mA/cm^2	165.1 mA/cm^2
Max. Cur. Density* (500Ω)	130.2 mA/cm^2	100.6 mA/cm^2	113.2 mA/cm^2
Max. Cur. Density* (800Ω)	91.9 mA/cm^2	73.9 mA/cm^2	78.6 mA/cm^2
Net Charge	0 µC	Same as Moventis	Same as Moventis
Avg. Phase Power* (300Ω)	0.077 W/phase	0.053 W/phase	0.060 W/phase
Avg. Phase Power* (500Ω)	0.068 W/phase	0.073 W/phase	0.076 W/phase
Avg. Phase Power* (800Ω)	0.052 W/phase	0.062 W/phase	0.060 W/phase
Avg. Phase Power Density* (300Ω)	0.60 W/cm^2/phase	0.42 W/cm^2/phase	0.48 W/cm^2/phase

Comparator	New Device	Predicate Device (Primary)	Predicate Device
Avg. Phase Power Density* (500Ω)	0.50 W/cm2/phase	0.58 W/cm2/phase	0.59 W/cm2/phase
Avg. Phase Power Density* (800Ω)	0.40 W/cm2/phase	0.48 W/cm2/phase	0.60 W/cm2/phase
Pulse Delivery Mode	Continuous	Same as Moventis	Same as Moventis
ON/OFF Times	ON/OFF Cycling Option	No Cycling	No Cycling
Current Path Options	Bipolar	Same as Moventis	Same as Moventis
Power Delivery	Coupled (fully integrated) receiver built into pIPG	Embedded receiver and coupled receiver in lumen	Same as Moventis
Transmit Frequency	915 MHz	Same as Moventis	Same as Moventis
Material	Platinum-iridium 90:10, Polyurethane 2363-55D	Same as Moventis	Same as Moventis
Sterile	Yes - ethylene oxide	Same as Moventis	Same as Moventis
Single-Use	Yes	Same as Moventis	Same as Moventis
Shelf Life	2 year	Same as Moventis	1 year
Complies with ISO 10993-1	Yes	Same as Moventis	Same as Moventis
Safety Testing Passed	Yes	Same as Moventis	Same as Moventis
MR Conditional	No	Yes	Yes
Accessories	Stylet and Introducer	Stylet, Guidewire, Introducer Assembly	Stylets, Guidewire, Tuohy Needle, Introducer Assembly
Software Level of Concern	Moderate	Same as Moventis	Same as Moventis
Programming Application	Not Applicable, ETx is pre-programmed	WaveCrest™	WaveCrest™

**formula-derived*

8. Biocompatibility Data

The materials, construction and intended use of Moventis PNS are comparable to the predicate devices and have a long history of safety with respect to biocompatibility. The biological safety of the pIPG (same as the Freedom-4 Stimulator, K141399) was evaluated in accordance to ISO 10993-1:2009 and guidance document Blue Book Memorandum G95-1 *Use of International Standard ISO-10993, and Biological Evaluation of Medical Devices: Part 1: Evaluation and Testing*. Under these, for the stated indications for use, the device was classified as a (C), implant device in contact with tissue/bone. The results for the biocompatible testing of the pIPG (same as the Freedom-4 Stimulator) for cytotoxicity, sensitization, irritation or intracutaneous reactivity, acute systemic toxicity, genotoxicity, implantation (4, 8, and 13 weeks), and subchronic toxicity demonstrated no negative impacts from the materials that are used in Moventis PNS. The pIPG materials in direct tissue contact include Pellethane 55D and Pt-Ir (90:10), both having an extensive record (previously cleared and approved) of chronic and carcinogenetic safety. The User Manual provided to the patient describes that ETx is intended to be worn on top of an article of clothing and not against the skin. The categorization by nature of body contact of the ETx is a "non-contacting device" and not included in the scope of ISO 10993-1:2009. Moventis PNS meets biological safety and compatibility requirements of ISO 10993-1:2009 & Blue Book Memorandum G95-1.

9. Non-Clinical Performance Data

Moventis PNS was tested to verify that the performance meets the system design requirements as well as all applicable voluntary standards. Moventis PNS complies with all design requirements and applicable voluntary standards.

ISO 14708-3:2017: The ETx (non-implantable) demonstrated compliance to the appropriate requirements of IEC 60601-1:2005 + A1:2012 and passed all tests for electrical safety, electromagnetic interference, and wireless coexistence.

For usability of the ETx (non-implantable and not connected to an electrical power source), demonstrated compliance to the appropriate requirements of IEC 62366:2015, meeting the acceptance criteria of the usability validation plan, mitigating risks as far as possible.

The risks associated with wireless communication with the implantable part of Moventis PNS are mitigated as far as possible by implementation of risk analysis, evaluation, control, and safety by design in compliance with ISO 14971:2019, protecting the patient from harm.

The packaging of Moventis PNS was verified to protect the devices from shock, stacking, vibration as well as temperature, pressure, and humidity variations commonly associated with storage and handling conditions in compliance with ISO 11607-1. The markings for Moventis PNS demonstrates compliance with durability and legibility requirements.

Moventis PNS is validated for ethylene oxide (EO) sterilization as specified by ISO 14708-3:2017 in compliance with ISO 11135:2014 and verified no unacceptable release of particulate matter at time of implantation. Moventis PNS has demonstrated biocompatibility in compliance with ISO 10993-1.

Moventis PNS is verified to protect patients from electrical harm as specified by ISO 14708-3:2017. By design, the direct current density at the surface of the electrodes is verified below 0.75µA/mm^2 and pIPG complies with requirements to withstand dielectric strength testing exposure.

Moventis PNS is verified to protect patients from heating harm and does not exceed heating limits. Moventis PNS has demonstrated safe operation in the presence of external influences including external defibrillation, ultrasound, and electromagnetic fields and have no irreversible damage following exposure to changes in electric fields. Where applicable, product labeling indicates medical procedures that are contraindicated for use with Moventis PNS. Residual risks associated with Moventis PNS is mitigated as far as possible.

Through design and device evaluation, Moventis PNS has demonstrated that any gradual, long term changes in materials do not result in unacceptable risks and has been mitigated as far as possible. Verification includes testing data with Moventis PNS, material selection, and risk evaluation.

The Moventis PNS pIPG was verified as functional after exposure to external defibrillation, complying with testing as specified by ISO 14708-3:2017.

Moventis PNS passed all criteria of the mechanical force test, demonstrating functionality following free-fall tests in accordance with IEC 60601-1:2005 + A1:2012, and showed no visible damage to the pIPG body or functional damage to the components. Mechanical testing of the pIPG included tensile testing, flex testing and torsion testing. Thus, the pIPGs comply with all mechanical design requirements. Moventis PNS demonstrated safe operation following exposure to electrostatic discharge in compliance with IEC 60601-1:2005 + A1:2012 and IEC 60601-1-2:2014. Moventis PNS demonstrated protection from damage caused by electrostatic discharge.

Moventis PNS passed all criteria of the atmospheric pressure and temperature test, exhibiting no change to device specification or damage following exposure to absolute pressure or changes in temperature.

IEC 60601-1: Moventis PNS was tested for compliance with IEC 60601-1:2005 + A1:2012 and demonstrated protection from temperature change, including shipping and storage temperature ranges, meeting the passing criteria of both of the visual and functional inspections following the testing. It showed no physical damage and was fully operational. Moventis PNS satisfies the outlined protection from temperature change design requirements and the applicable standard, IEC 60601-1. Moventis PNS met the passing criteria of both of the visual and functional inspections following the atmospheric pressure change testing, showed no physical damage and was fully operational. Moventis PNS satisfies the outlined atmospheric pressure change design requirements and the applicable standard, IEC 60601-1. For push, drop, impact and mold stress relief testing of Moventis PNS, it was determined through testing that the design is robust to withstand expected damage in accordance with general safety standards, meeting the passing criteria of both of the visual and functional inspections following the testing, showing no physical damage and full operation. Moventis PNS satisfies the outlined push, drop, impact, and mold stress relief design requirements and the applicable standard, IEC 60601-1. For the identification, marking and documents of Moventis PNS, it was determined through an analysis of the labeling that compliance with the requirements of the standard is demonstrated. All requirements and markings are clearly identified and viewable either from the packaging product or within the accompanying documents. For the means of protection, creepage distances, and air clearances of Moventis PNS was determined through an analysis of the design that the system satisfies the requirements of the applicable standard, IEC 60601-1.

IEC 60529: Moventis PNS was tested for compliance with IEC 60529. For testing the ingress of water, Moventis PNS met the passing criteria of both of the visual and functional inspections following the testing, showing no physical damage and was fully operational. Thus, satisfying the outlined Ingress of Water design requirements and the applicable standard IEC 60529. For particulate matter testing, Moventis PNS met the passing criteria of both of the visual and functional inspections following the testing, showing no physical damage and was fully operational. Thus, satisfying the outlined Particulate Matter design requirements and the applicable standard, IEC 60529.

IEC 60601-1-2: Moventis PNS was tested for compliance with IEC 60601-1-2. For electromagnetic compatibility testing, Moventis PNS met all acceptance criteria for emissions, low-frequency magnetic fields, immunity, electrostatic discharge, radiated RF electromagnetic fields, and magnetic fields. For all tests, Moventis PNS operated within all test limits and showed no physical damage and was fully operational. Thus, satisfying the IEC 60601-1-2 standard.

Moventis PNS complies with the applicable standards for neurostimulators, electrical safety, electromagnetic interference and compatibility, biocompatibility, packaging, and sterilization, meeting all the requirements for overall design, sterilization, biocompatibility, and electrical safety confirms that the output meets the design inputs and specifications, passing all testing stated above as shown by the acceptable results obtained. Moventis PNS passed all the testing in accordance with national and international standards.

Following performance testing, it has been determined that Moventis PNS is substantially equivalent to legally marketed predicate devices for the therapeutic relief for chronic, intractable pain of peripheral nerve origin.

10. Clinical Performance Data

There was no clinical testing required to support the medical device, as the indications for use are equivalent to the legally marketed predicate devices. These types of devices, including the legally marketed predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in K200848 supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to legally marketed predicate devices when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Moventis PNS has the same intended use as the legally marketed predicate devices. Performance tested verified that Moventis PNS complies with all applicable voluntary standards such as IEC 60601-1, ISO 14708-3, and IEC 60529. Moventis PNS also meets the design requirements where no applicable standard could be used. This includes pIPG body durability testing, programmable parameters, as well as performance of the ETx. There were no recognized performance standards for this device. There was no clinical testing performed on this device since performance testing demonstrated similar performance as the legally marketed predicate devices, and materials for the pIPG are the same as the legally marketed predicate devices.

It has been shown in K200848 that the difference between Moventis PNS and the legally marketed predicate devices do not raise any questions regarding safety and effectiveness. Moventis PNS, as designed and manufactured, is determined to be substantially equivalent to the referenced legally marketed predicate devices.