August 27, 2021

Neuspera Medical Inc.
Alexander Yeh
Founder and Chief Technology Officer
51 Daggett Dr.
San Jose, California 95134

Re: K202781
Trade/Device Name: Neuspera Neurostimulation System (NNS)
Regulation Number: 21 CFR 882.5870
Regulation Name: Implanted Peripheral Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: GZF
Dated: August 25, 2021
Received: August 25, 2021

Dear Alexander Yeh:

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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202781

Device Name
Neuspera Neurostimulation System (NNS)

Indications for Use *(Describe)*
The Neuspera Neurostimulation System (NNS) 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 system is not intended to treat pain in the craniofacial region.

The Neuspera Neurostimulation System (NNS) is also used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) implant.

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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SECTION 8: 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K202781

Applicant Information:

Owner Name: Neuspera Medical Inc
Address: 51 Daggett Dr.
San Jose, CA 95134

Contact Person: Alexander Yeh, Ph.D
Phone Number: (888) 846-8332

Date Prepared: 9/21/2020

Device Information:

Trade/Proprietary Name: Neuspera Neurostimulation System
Common/Usual Name: Neuspera Neurostimulation System
Product Code: GZF
Regulation number: 21 CFR 882.5870: Stimulator, peripheral nerve, implanted (Pain Relief)
Class: Class II
Device Classification Panel: Neurology

Predicate Devices:

The Neuspera Neurostimulation System is substantially equivalent in intended use and method of operation to the cleared Nalu Neurostimulator System (K183579).

Device Description:

The Neuspera Neurostimulation System is used for peripheral nerve stimulation to provide therapeutic relief for chronic, intractable pain of peripheral nerve origin. The System consists of an implantable pulse generator (IPG), electrode array, surgical implant tools, wireless worn transmitter, clinician programmer and a patient controller. The implantable pulse generator is a miniature implanted neurostimulator, powered by an externally worn wireless transmitter device which contains a rechargeable battery.

Similar to the predicate, the Neuspera Neurostimulation therapy utilizes pulsed electrical current to create an energy field that acts on the targeted nerve to inhibit the transmission of pain signals to the brain. The Neuspera Neurostimulation System may also be used during the trial period before recommendation for permanent implant.

The Neuspera Neurostimulation System (NNS) System is comprised of the following components:

System Component	Description
Neuspera Implanted Pulse Generator (IPG) Or Neuspera Implanted Microstimulator	The implanted Neuspera Neurostimulation System (NNS) includes a miniaturized implantable neurostimulator (approximately 17mm long by 2.3 mm diameter at its widest point) combining a receiver and a hermitically sealed pulse generator. The IPG/Microstimulator is a hermitically sealed electronic package (0.02 cc) consisting of a highly integrated electronic circuit with a custom ASIC (application specific integrated circuit) and a flex circuit interconnect. This package harvests the received energy, charges an internal energy bank, and manages power/communication. The energy bank is used by the internal stimulation waveform generator to generate stimulation pulses based upon the digitally received programming parameters. Hermetic feedthroughs conduct the stimulation waveform from the stimulation implantable pulse generator to the electrode array described below.
Electrode Array	The electrode array is an implantable and attached to the IPG through hermetic feedthroughs connectors. The electrode array is designed to deliver electrical pulses to the nerve via an array of four cylindrical electrodes at the distal end of the device.
Surgical/Implant Tools	The tools provided in the Neuspera Neurostimulation System (NNS) Kit are used to introduce and implant the neurostimulator. A needle along with imaging guidance is used to locate the targeted nerve. Next, the needle is replaced with a guidewire. An incision is made at the skin surface adjacent to the guidewire. Next, a pre-dilator is inserted around the guidewire to dilate the path to the nerve. The pre-dilator is then removed and replaced with an introducer and dilator. The dilator and guidewire are then removed. The implant is tunneled through the introducer (sheath) using a connected pushrod. The PTFE tether at the proximal end of the implant is cut and placed in a subcutaneous pocket.

System Component	Description
Externally Worn Wireless Transmitter	The charging system consists of an externally worn wireless transmitter that is rechargeable. Power is delivered to the implanted neurostimulator using Neuspera's proprietary mid-field powering technology. The Wireless Transmitter is worn in proximity to the implanted neurostimulator and held in position by custom designed garments. The Wireless Transmitter is controlled by custom software applications (referred to as the Clinician Programmer and the Patient Controller) running on off-the-shelf portable hardware (i.e., Apple iPad and Apple iPod Touch, respectively). The rechargeable battery of the Wireless Transmitter is charged by an off-the-shelf charging pad.
Clinician Programmer and Patient Controller	The clinician programmer (Programmer) enables management of the Wireless Transmitter associated with the patient's neurostimulator, programming a patient's stimulation therapy, review of the patient's therapy statistics, and connection of a patient controller (Controller) to a patient's Wireless Transmitter. The Programmer runs Neuspera's propriety programmer software on a commercially available Apple iPad. The iPad runs in kiosk mode, which disables non-essential programs and functions. The Patient Controller is an Apple iPod Touch which runs the Neuspera patient controller software application ("Neuspera App"). The iPod Touch comes with its own USB/wall charging accessories. The iPod runs in kiosk mode, which disables non- essential programs and functions. The Controller is used by the patient to turn his/her Wireless Transmitter on/off, adjust stimulation amplitude (within limits set by the physician), and select which of the physician pre-programmed stimulation programs to use. The user can also monitor the Wireless Transmitter battery level, view his/her program use history, and adjust the Wireless Transmitter for airplane and international travel.

Intended Use:

The Neuspera Neurostimulation System (NNS) 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 system is not intended to treat pain in the craniofacial region.

The Neuspera Neurostimulation System (NNS) is also used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) implant.

Summary of Technological Characteristics in Comparison to Predicate Device:

Neuspera Neurostimulation System (NNS and the predicate device Nalu Neurostimulation System for Peripheral Nerve Stimulation (K183579) have similar indication for use, technological characteristics and performance. Both the subject device and the predicate devices are designed to provide 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. Both systems are not intended to treat pain in the craniofacial region. The minor differences in wording for intended use statements of the respective products do not alter the intended patient or clinical effect, and, therefore, the Neurostimulator System is substantially equivalent with respect to intended use. In addition, the differences listed in tables below do not present any new issues of safety or effectiveness. Moreover, performance testing demonstrates that the Neuspera Neurostimulation System performs in a substantially equivalent manner.

	Table 1: Predicate Device Comparison Matrix			
	Neuspera Neurostimulation System (Subject Device)	**Nalu Neurostimulation System (Primary Predicate)**	**Bioness StimRouter Neuromodulation System (Reference Device)**	**Analysis of Technological Differences from Primary Predicate**
510(k)	K202781	K183579	K200482	N/A
Product Code and class	GZF, Class II	Same	Same	Same
Regulation number	21 CFR §882.5870	Same	Same	Same
Classification name	Stimulator, Peripheral Nerve, Implanted (pain relief)	Same	Same	Same
Intended Use	Stimulation of peripheral nerves for chronic, intractable pain	Same	Same	Same
Indications for Use	The Neuspera Neurostimulation System (NNS) 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 Neuspera Neurostimulation System (NNS) is not intended to treat pain in the craniofacial region. The Neuspera Neurostimulation System (NNS) is also used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) implant.	This system 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 system is not intended to treat pain in the craniofacial region. The trial devices are solely used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) device.	The StimRouter Neuromodulation System™ is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as an adjunct to other modes of therapy (e.g., medications). The StimRouter is not intended to treat pain in the craniofacial region.	Differences in wording do not affect safety and effectiveness of intended use
Prescription Use?	Yes	Same	Same	Same
Implant site	Adjacent to nerves peripheral to central nervous system, excluding craniofacial region	Same	Same	Same
Environmental Use	Hospital, Home	Same	Same	Same
Intended Clinician	Orthopedic, Neurosurgeon, Anesthesiologist	Same	Same	Same
Intended User	Physician, Layperson	Same	Same	Same
Mode of Action	Radio Frequency (RF) wireless transmission of energy to charge implanted energy source with stimulation pulse generator to produce stimulation at stimulator electrodes.	Radio Frequency (RF) wireless transmission of energy to produce stimulation at stimulator electrodes	DC conductive coupling from external patch pulse generator to implanted lead	Differences do not affect safety and effectiveness of intended use
Software Level of Concern	Moderate	Same	Same	Same

	Table 2: Implanted Components			
	Neuspera Neurostimulation System *(Subject Device)*	**Nalu Neurostimulation System (Primary Predicate)**	**Bioness StimRouter Neuromodulation System (Reference Device)**	**Analysis of Technological Differences from Primary Predicate**
Dimensions	IPG: 2.33mm diameter, electrode array 1.3mm diameter, 5.1 cm total length	Lead = 1.30 mm diameter, 40 or 60 cm length, IPG = 28 x 11 x 4.9 mm	Lead = 1.20 mm diameter, 15 cm length	Differences do not affect safety and effectiveness of intended use
Configuration	Implanted antenna receiver, energy storage capacitor, stimulation pulse generator coupled with electrode arrays	Embedded receiver, flexible circuit board	Implanted electrode array and external pulse generator	Differences do not affect safety and effectiveness of intended use
Implant site	Peripheral nerves, excluding craniofacial region	Same	Same	Same
Electrical components	Embedded receiver, flexible circuit board with energy storage and stimulation pulse generator	Same	Embedded receiver	Differences do not affect safety and effectiveness of intended use
Power Delivery	Radio frequency transmission receiver	Coupled receiver radio frequency transmission	DC transcutaneous coupling	Differences do not affect safety and effectiveness of intended use
Electrode Material	Platinum-iridium 90:10	Same	Same	Same
Insulation Body Material	Pellethane 2363-55D	Same	Silicone	Differences do not affect safety and effectiveness of intended use
Electrode Array Diameter	1.30 mm	1.30 mm	1.20 mm	Differences do not affect safety and effectiveness of intended use
Electrode Array length	21mm	52 mm	5 mm	Differences do not affect safety and effectiveness of intended use
No. of Electrodes per array	4	8	3	Differences do not affect safety and effectiveness of intended use
Individual Electrode length	3mm	Same	Same	Same
Electrode surface area	12.25 mm2	12.25 mm3	6.3 mm2	Same
Sterilization	Ethylene Oxide	Same	Same	Same

	Table 3: Therapy			
	Neuspera Neurostimulation System *(Subject Device)*	**Nalu Neurostimulation System (Primary Predicate)**	**Bioness StimRouter Neuromodulation System (Primary Predicate)**	**Analysis of Technological Differences from Primary Predicate**
Pulse Frequency	4 to 130 Hz	2 to 1500 Hz	1 to 200 Hz	Differences do not affect safety and effectiveness of intended use
Pulse Width	105 to 960 µs	12 to 1000 µs	70 to 500µs	Differences do not affect safety and effectiveness of intended use
Current/Voltage Regulated	Voltage	Current	Current (dependent on pick-up ratio at implant)	Differences do not affect safety and effectiveness of intended use
Output Current (300 Ohms)	0 to 5.73 mA*	0 to 10.2 mA	0 to 5 mA***	Differences do not affect safety and effectiveness of intended use
Output Current (500 Ohms)	0 to 5.44 mA*	0 to 10.2 mA	0 to 5 mA***	Differences do not affect safety and effectiveness of intended use
Output Current (800 Ohms)	0 to 5.20 mA*	0 to 10.2 mA	0 to 5 mA***	Differences do not affect safety and effectiveness of intended use
Waveform	charge balanced (delayed) biphasic asymmetrical	Same	charge balanced (delayed) biphasic asymmetrical or symmetrical	Same
Pulse Shape	Decaying Exponential	Same	Same	Same
Maximum phase charge (300 Ohms)	2.88 µC/pulse**	6.8 µC/pulse	3 µC/pulse***	Differences do not affect safety and effectiveness of intended use
Maximum phase charge (500 Ohms)	2.74 µC/pulse**	6.4 µC/pulse	3 µC/pulse***	Differences do not affect safety and effectiveness of intended use
Maximum phase charge (800 Ohms)	2.43 µC/pulse**	4.7 µC/pulse	3 µC/pulse***	Differences do not affect safety and effectiveness of intended use
Maximum charge density (300 Ohm)	23.5 µC/cm2**	53.1 µC/cm2	15.9 µC/cm2***	Differences do not affect safety and effectiveness of intended use
Maximum charge density (500 Ohm)	22.4 µC/cm2**	50.3 µC/cm2	15.9 µC/cm2***	Differences do not affect safety and effectiveness of intended use
Maximum charge density (800 Ohm)	19.8 µC/cm2**	36.9 µC/cm2	15.9 µC/cm2***	Differences do not affect safety and effectiveness of intended use

	Table 3: Therapy			
	Neuspera Neurostimulation System *(Subject Device)*	**Nalu Neurostimulation System (Primary Predicate)**	**Bioness StimRouter Neuromodulation System (Primary Predicate)**	**Analysis of Technological Differences from Primary Predicate**
Maximum current density (300 Ohm)	46.8 mA/cm2*	106.1 mA/cm2	26.5 mA/cm2***	Differences do not affect safety and effectiveness of intended use
Maximum current density (500 Ohm)	44.4 mA/cm2*	100.6 mA/cm2	26.5 mA/cm2***	Differences do not affect safety and effectiveness of intended use
Maximum current density (800 Ohm)	42.4 mA/cm2*	73.9 mA/cm2	26.5 mA/cm2***	Differences do not affect safety and effectiveness of intended use
Net Charge	0 µC	Same	Same	Same
Pulse Delivery Mode	Continuous	Same	Same	Same
Current Path options	Bipolar	Same	Same	Same
Program Cycle	Cycle through programs	Same	Same	Same
Pulse Pattern	Fine tuning of pulse patterns	Same	Same	Same
Dosage Time	Cycling ON/OFF 1 second-1 day	Same	Same	Same

**** measured with typical therapy pulse width of 240us***
***** measured with maximum pulse with of 960us***
****** unreported test impedance conditions***

Summary of Non-Clinical Testing:

The Neuspera Neurostimulation System design verification and validation consisted of functional, performance and MRI testing. The verification and validation testing were performed according to the product specifications as well as to applicable ISO standards. Design verification and validation testing was performed to ensure that the Neurostimulator System met design specifications and customer requirements. Non-clinical testing activities includes but not limited to the following:

- Visual tests
- Dimensional measurement tests
- Tensile tests
- Mechanical Tests
- Electrical Test
- EMC Tests
- MRI Tests

Full test reports have been included within the submission. Additionally, test summaries have been prepared and are presented within the applicable submission section. Per Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards. Table below identifies the standards that have been referenced within this submission.

Standard Name	FDA recognition number:	Standard Title
ES60601-1:2005/(R)2012 and A1:2012,	19-4	C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
HA60601-1-11:2015	19-16	Medical Electrical Equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2015 MOD)
10993-1 Fifth edition 2018-08	2-258	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
11135 Second edition 2014-07-15	14-452	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
14708-3 Second edition 2017-04	17-15	Implants for surgery - Active implantable medical devices - Part 3: Implantable neurostimulators

Biocompatibility Testing:

Biocompatibility testing for the Neuspera Neurostimulation System has been completed in accordance with the International Standard IS0-10993-1:2018 " Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process ". Biocompatibility testing was based upon the categorization of the different body- contacting components and duration of the Neuspera PNS system. These categories are as follows:

- Implant is biocompatible per ISO 10993-1:2018 for long-term implant (>30 days)
- All implant tools are biocompatible for limited duration tissue contact (<24 hours)

Testing included: genotoxicity, cytotoxicity, sensitization, irritation or intracutaneous reactivity, systematic toxicity, implant studies, and chemical characterization. Biocompatibility was demonstrated.

Summary of Animal Testing:

Two GLP animal studies were conducted to evaluate the safety and performance of the Neuspera Neurostimulation System.

The first animal study showed that the overall implant and removal of the non- functional devices at 2-weeks and 90-days was completed easily without sequelae. The objective of the second GLP animal study was intended to evaluate the safety and performance of the Wireless Transmitter as well as to validate the use of the Neuspera Implant Kit. The study showed that the surgical procedure was safe, and the Neuspera Neurostimulation system performed as expected.

Summary of Clinical Testing:

Clinical evaluation is not required for the Neuspera Neurostimulation System as the indications for use are equivalent to the legally marketed predicate device and referenced device. These types of devices, including versions of the legally marketed predicate device, have been on the market for many years with a proven safety and efficacy for the use of the device. Therefore, Neuspera determined that bench and non-clinical testing are sufficient to demonstrate that the Neuspera Neurostimulation System is as safe and effective as the predicate device.

Substantial equivalence:

The results of bench testing and compliance with applicable standards provide reasonable assurance that the Neuspera Neurostimulation System has been designed and tested to assure conformance to the requirements for its indications for use.

Neuspera considers the Neuspera Neurostimulation System to be substantially equivalent to the legally marketed predicate device because it has similar intended use and similar indications, technological characteristics and performance. The differences between the subject device and the predicate device do not alter the intended patient or clinical effect and, therefore, the Neuspera Neurostimulation System is substantially equivalent to currently marketed predicate device.