April 11, 2023

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

Re: K221303
Trade/Device Name: Neuspera Nuity System
Regulation Number: 21 CFR 882.5870
Regulation Name: Implanted Peripheral Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: GZF
Dated: March 8, 2023
Received: March 9, 2023

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,

Vivek J. Pinto -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K221303

Device Name
Neuspera Neurostimulation (Nuity™) System

Indications for Use *(Describe)*

The Neuspera Nuity™ 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 Nuity™ 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: K221303

Applicant Information:

Submitter	Neuspera Medical Inc
Address:	51 Daggett Dr. San Jose, CA 95134
Contact Person:	Alexander Yeh, Ph.D
Phone Number:	(888) 846-8332
Date Prepared:	5/2/2022

Device Information:

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

Predicate Device:

The Neuspera Nuity™ System is substantially equivalent in intended use and technological characteristics to the cleared Neuspera Neurostimulation System (K202781).

Reference Device:

Nalu Neurostimulation System for Peripheral Nerve Stimulation (K183579)

Device Description:

The Neuspera Nuity™ 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, a patient controller, and undergarments. The implantable pulse generator is a miniature implanted neurostimulator, powered by an externally worn wireless transmitter device which contains a rechargeable battery.

Same as the predicate, the Neuspera Nuity™ System 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 Nuity™ System may also be used during the trial period before recommendation for permanent implant.

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

System Component	Description
Neuspera Implanted Pulse Generator (IPG) Or Neuspera Implanted Microstimulator	The implanted Neuspera Nuity™ System (NNS) includes a miniaturized implantable neurostimulator (approximately 17 mm long by 2.3 mm diameter at its widest point) combining a receiver and a hermetically sealed pulse generator. The IPG/Microstimulator is a hermetically 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 Nuity™ 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 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 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.

Indication for Use:

The Neuspera Nuity™ 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 Nuity™ 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:

All of the physical attributes for the proposed Neuspera Nuity™ Neurostimulation System and the predicate and reference devices share the same technological characteristics and have no differences that would impact safety or effectiveness. Bench testing was conducted to demonstrate changes to the therapeutic attributes are within parameters of reference devices. In conclusion, testing and comparison of characteristics in table below demonstrate that the subject and predicate device are substantially equivalent.

	Table 1: Subject and Predicate Devices Comparison Matrix			
	Neuspera Nuity™ System (Subject Device) K221303	**Neuspera Neurostimulation System (Primary Predicate) K202781**	**Nalu Neurostimulation System (Reference Device) K183579**	**Analysis of Technological Differences from Primary Predicate**
510(k)	K221303	K202781	K183579	N/A
Product Code and class	GZF, Class II	Same	Same	Same
Regulation number	21 CFR §882.5870	Same	Same	Same
Classification name	Implanted peripheral nerve stimulator for pain relief	Same	Same	Same
Intended Use	Stimulation of peripheral nerves for chronic, intractable pain	Same	Same	Same
Indications for Use	The Neuspera Nuity™ 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 Nuity™ System (NNS) is not intended to treat pain in the craniofacial region. The Neuspera Nuity™ System (NNS) is also used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) implant.	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.	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

	Table 1: Subject and Predicate Devices Comparison Matrix			
	Neuspera Nuity™ System (Subject Device) K221303	**Neuspera Neurostimulation System (Primary Predicate) K202781**	**Nalu Neurostimulation System (Reference Device) K183579**	**Analysis of Technological Differences from Primary Predicate**
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 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	Same as K202781
Software Level of Concern	Moderate	Moderate	Moderate	Same

	Table 2: Implanted Components Comparison			
	Neuspera Nuity™ System (Subject Device) K221303	**Neuspera Neurostimulation System (Primary Predicate) K202781**	**Nalu Neurostimulation System (Reference Device) K183579**	**Analysis of Technological Differences from Primary Predicate**
Dimensions	IPG: 2.33 mm diameter, electrode array 1.3 mm diameter, 4.5-5.2 cm total length	IPG: 2.33 mm diameter, electrode array 1.3 mm diameter, 5.1 cm total length	Lead = 1.30 mm diameter, 40 or 60 cm length, IPG = 28 x 11 x 4.9 mm	The subject devices consist of 2 lengths (including distal strain relief): 30 mm and 35 mm electrode array lengths. The electrode array length of the predicate (not including distal strain relief) is 34 mm. The proximal circuitry housing assembly remains the same length between the subject and predicate devices. The difference in lengths of the electrode arrays are negligible as

	Table 2: Implanted Components			
	Neuspera Nuity™ System (Subject Device) K221303	**Neuspera Neurostimulation System (Primary Predicate) K202781**	**Nalu Neurostimulation System (Reference Device) K183579**	**Analysis of Technological Differences from Primary Predicate**
				the therapy output remains the same between the subject devices and the predicate device.
Configuration	Implanted antenna receiver, energy storage capacitor, stimulation pulse generator coupled with electrode arrays	Implanted antenna receiver, energy storage capacitor, stimulation pulse generator coupled with electrode arrays	Embedded receiver, flexible circuit board	Same as K202781
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	Same	Same
Power Delivery	Radio frequency transmission receiver	Same	Coupled receiver radio frequency transmission	Same as K202781
Electrode Material	Platinum-iridium 90:10	Same	Same	Same
Insulation Body Material	Pellethane 2363-55D	Same	Same	Same
Electrode Array Diameter	1.30 mm	Same	Same	Same
Electrode Array length (Measured Start of First to End of Last Electrode)	21 mm	Same	52 mm	Same as K202781
No. of Electrodes per array	4	Same	8	Same as K202781
Individual Electrode length	3 mm	Same	Same	Same
Electrode surface area	12.25 mm^2	Same	12.25 mm^3	Same
Sterilization	Ethylene Oxide	Same	Same	Same

	Table 3: Therapy Comparison			
	Neuspera Nuity™ System (Subject Device) K221303	***Neuspera Neurostimulation System (Primary Predicate) K202781***	**Nalu Neurostimulation System (Reference Device) K183579**	**Analysis of Technological Differences from Primary Predicate**
Pulse Frequency	2 to 1500 Hz	4 to 130 Hz	2 to 1500 Hz	Neuspera Nuity pulse frequency range covers predicate device and is within range of reference device. Therefore, differences do not affect safety and effectiveness
Pulse Width	15 to 960 µs	105 to 960 µs	12 to 1000 µs	Neuspera Nuity pulse width range covers predicate device and is within range of reference device. Therefore, differences do not affect safety and effectiveness
Current/Voltage Regulated	Voltage or Current	Voltage	Current	Adjustable between regulation mode of both predicate and reference devices. Therefore, differences do not affect safety and effectiveness.
Output Current (300 Ohms)	0 to 5.73 mA*	Same	0 to 10.2 mA	Same as K202781
Output Current (500 Ohms)	0 to 5.44 mA*	Same	0 to 10.2 mA	Same as K202781
Output Current (800 Ohms)	0 to 5.20 mA*	Same	0 to 10.2 mA	Same as K202781
Waveform	charge balanced (delayed) biphasic asymmetrical	Same	Same	Same
Pulse Shape	Decaying Exponential	Same	Same	Same
Maximum phase charge (300 Ohms)	2.88 µC/pulse**	Same	6.8 µC/pulse	Same as K202781
Maximum phase charge (500 Ohms)	2.74 µC/pulse**	Same	6.4 µC/pulse	Same as K202781
Maximum phase charge (800 Ohms)	2.43 µC/pulse**	Same	4.7 µC/pulse	Same as K202781

	Table 3: Therapy Comparison			
	Neuspera Nuity System (Subject Device) K221303	***Neuspera Neurostimulation System (Primary Predicate) K202781***	**Nalu Neurostimulation System (Reference Device) K183579**	**Analysis of Technological Differences from Primary Predicate**
Maximum charge density (300 Ohm)	23.5 μC/cm^2**	Same	53.1 μC/cm^2	Same as K202781
Maximum charge density (500 Ohm)	22.4 μC/cm^2**	Same	50.3 μC/cm^2	Same as K202781
Maximum charge density (800 Ohm)	19.8 μC/cm^2**	Same	15.9 μC/cm^2***	Same as K202781
Maximum current density (300 Ohm)	46.8 mA/cm^2*	Same	26.5 mA/cm^2***	Same as K202781
Maximum current density (500 Ohm)	44.4 mA/cm^2*	Same	26.5 mA/cm^2***	Same as K202781
Maximum current density (800 Ohm)	42.4 mA/cm^2*	Same	26.5 mA/cm^2***	Same as K202781
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:

Non-clinical testing activities for the Neuspera Nuity™ System includes but are 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 Nuity 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.

Substantial equivalence:

The subject device of this 510(k) is substantially equivalent to the predicate since it has identical intended use and the change in software, hardware, and differences in technological characteristics do not raise new questions of safety and effectiveness.