September 6, 2019

Nalu Medical, Inc.
Michele Chin-Purcell
VP Regulatory Affairs and Quality Assurance
2320 Faraday Ave. Suite 100
Carlsbad, California 92008

Re: K191435
Trade/Device Name: IPG, integrated, 25/40 cm, single, tined, IPG, 2 cm, single 4, Lead (25/40 cm, 4, tined), Extension - 4
Regulation Number: 21 CFR 882.5870
Regulation Name: Implanted Peripheral Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: GZF
Dated: August 5, 2019
Received: August 7, 2019

Dear Michele Chin-Purcell:

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,

Robert Kang, PharmD
Acting 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)*
K191435

Device Name
Nalu Neurostimulation System for PNS

Indications for Use *(Describe)*
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.

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
K191435

Submission Sponsor

Nalu Medical, Incorporated
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Contact: Michele Chin-Purcell, Vice President of Regulatory Affairs and Quality Assurance

Date Prepared

August 30, 2019

Device Identification

Trade/Proprietary Name: Nalu Neurostimulation System, 4 Contact PNS System
Common/Usual Name: Peripheral Nerve Stimulator
Product Code: GZF
Regulation number: 21 CFR 882.5870: Stimulator, peripheral nerve, implanted (Pain Relief)
Class: Class II
Device Classification Panel: Neurology

Legally Marketed Predicate Device(s)

Nalu Neurostimulation System for Peripheral Nerve Stimulation (K183579)

For areas where slight differences occur between the Nalu Neurostimulation system and the primary predicate (K183579), substantial equivalence to other reference devices in this same product code is demonstrated. These reference devices were used as part of the predicate history to the primary predicate in this submission. The history of the predicates is summarized in Table below:

Predicate history of the proposed primary predicate

Device	510(k)	Predicate(s) used for clearance
StimQ Peripheral Nerve Stimulator (PNS) System **(Reference Devices)**	K152178	Stimwave Freedom SCS (K150517) Medtronic Mattrix 3271/3272 (K934065) Medtronic Xtrel, 3425 (K883780)
StimQ Peripheral Nerve Stimulator (PNS) System **(Reference Devices)**	K171366	K152178
Nalu Neurostimulation System for PNS	K183579	K171366

Device	510(k)	Predicate(s) used for clearance
(Primary Predicate)		

The 510(k) history of the StimQ PNS System includes design changes over time. The original Medtronic devices are part of the predicate history of the StimQ PNS System and are also used as reference devices in this document.

Device Description

This submission will add 4 stimulation contact options to the predicate Nalu Neurostimulation System (also referred to as the "Nalu PNS System"). The Nalu PNS System is used for peripheral nerve stimulation to provide therapeutic relief for chronic, intractable pain of peripheral nerve origin. The Nalu PNS System incorporates a miniature implanted neurostimulator, powered by an externally worn Therapy Disc device. The Nalu Neurostimulation therapy utilizes pulsed electrical current to create an energy field that acts on the peripheral nerves to inhibit the transmission of pain signals to the brain. The Nalu PNS System may be implanted following a successful trial period using the Nalu PNS trial system.

The leads that were cleared with the Nalu PNS System featured 8 stimulation contacts. This submission will provide an optional use of leads with 4 stimulation contacts.

The 4 Contact PNS System include the following subject devices in this submission:

1. 4 Contact Nalu Implantable Pulse Generator	The implantable pulse generator (IPG) provides electrical stimulation pulses that are transmitted through the leads to the desired peripheral nerve. The IPG is available in two different implant architectures: an "integrated" system with a single pre-attached lead (available in two lengths) and a "ported" system where a single lead (available in two effective lengths) may be attached, via connector ports. The hermetic IPG housing includes a ceramic enclosure and a feedthrough connected internally to a printed circuit board assembly. Wires leaving the IPG are encapsulated in polyurethane and a silicone over mold forms the final biocompatible surface of the IPG for direct patient tissue contact.
2. 4 Contact Leads/ Lead Extension	Leads are implantable and are designed to deliver electrical pulses to the peripheral nerve via an array of four cylindrical electrodes at the distal end. Leads may be integrated with or connected to the IPG. The leads use polyurethane insulation with Pt/Ir electrodes. The leads are secured in place with tines designed into the lead body. A 4 contact Lead Extension is also available which connects to the proximal end of the lead to extend the lead subcutaneously.

Indications for Use Statement

"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 Indications for Use statement for the 4 Contact PNS System are identical to the predicate Nalu Neurostimulation System. The intended use is unchanged from the predicate.

Substantial Equivalence Discussion

The following tables compare the 4 Contact PNS System to the predicate device 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: Substantial Equivalence Table – General and Implanted Components

	4 Contact PNS System (Subject Device)	Nalu Neurostimulation System (Primary Predicate)	StimQ PNS System (Reference Device)	StimQ PNS System (Reference Device)	Medtronic Mattrix 3271/3272 (Reference Device)	Medtronic Xtrel 3425 (Reference Device)	Analysis of Technological Differences from Primary Predicate
510(k)	K191435	K183579	K171366	K152178	K934065	K883780	NA
Product Code and class	GZF, Class II	Same	Same	Same	GZF and GZB	GZB	Same
Regulation number	21 CFR §882.5870	Same	Same	Same	Same, plus 21 CFR 882.5880	Same	Same
Classification name	Stimulator, Peripheral Nerve, Implanted (pain relief)	Same	Same	Same	Same plus Stimulator, Spinal Cord, Implanted (Pain Relief)	Same	Same
Intended Use	Stimulation of peripheral nerves for chronic, intractable pain	Same	Same	Same	Same, plus Stimulation of spinal cord for chronic, intractable pain	Same	Same
Indications for Use	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 multidisciplina	Same	The StimQ Peripheral Nerve Stimulator (PNS) 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 StimQ PNS System is not intended to treat		Indicated as an aide in the management of chronic, intractable pain of the trunk or limbs		Same

	4 Contact PNS System (Subject Device)	Nalu Neurostimulation System (Primary Predicate)	StimQ PNS System (Reference Device)	StimQ PNS System (Reference Device)	Medtronic Mattrix 3271/3272 (Reference Device)	Medtronic Xtrel 3425 (Reference Device)	Analysis of Technological Differences from Primary Predicate
	ry 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.		pain in the craniofacial region. The StimQ Trial Lead Kit is only used in conjunction with the StimQ Stimulator Receiver Kit. 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.				
Prescription Use?	Yes	Same	Same	Same	Same	Same	Same
Implant site	Peripheral nerves, excluding craniofacial region	Same	Same	Same	Same	Same	Same
Environmental Use	Hospital, Home	Same	Same	Same	Same	Same	Same
Intended Clinician	Orthopedic, Neurosurgeon Anesthesiologist	Same	Same	Same	Same	Same	Same
Intended User	Physician, Layperson	Same	Same	Same	Same	Same	Same
Mode of Action	Radio Frequency (RF) wireless transmission of energy to produce stimulation at stimulator electrodes.	Same	Same	Same	Same	Same	Same

	4 Contact PNS System (Subject Device)	Nalu Neurostimulation System (Primary Predicate)	StimQ PNS System (Reference Device)	StimQ PNS System (Reference Device)	Medtronic Mattrix 3271/3272 (Reference Device)	Medtronic Xtrel 3425 (Reference Device)	Analysis of Technological Differences from Primary Predicate
Software Level of Concern	Moderate	Same	Same	Same	Unreported	Unreported	Same
Sterilization	Ethylene Oxide	Same	Same	Same	Same	Same	Same

	4 Contact PNS System (Subject Device)	Nalu Neurostimulation System (K183579) (Primary Predicate)	StimQ PNS System (K171366) (Reference Predicate)	StimQ PNS System (K152178) (Reference Device)	Medtronic Mattrix 3271/3272 (K934065) (Reference Device)	Medtronic Xtrel 3425 (K883780) (Reference Device)	Analysis of Technological Differences from Primary Predicate
Electrode Material	Platinum-iridium 90:10	Same	Same	Same	Same	Same	Same
Insulation Body Material	Pellethane 2363-55D	Same	Same	Same	Same	Same	Same
Cable features	Coiled Wires	Multilumen tube	Multilumen tube	Multilumen tube	Coiled Wires	Coiled Wires	Differences do not affect safety and effectiveness of intended use
Lead length	25 cm, 40 cm	40 cm, 60 cm	44 cm	45 cm	30 to 110 cm	30 to 110 cm	Differences do not affect safety and effectiveness of intended use
Diameter	1.30 mm	1.30 mm	1.35 mm	1.35 mm	1.3 mm	1.3 mm	Same
Electrode Array length	21 mm	52 mm	24 mm (FRE-4) 52 mm (FRE-8)	24 mm	24 mm	24 mm	Differences do not affect safety and effectiveness of intended use
No. of Electrodes, per lead	4	8	4 (FRE-4) 8 (FRE-8)	4	Same	Same	Differences do not affect safety and effectiveness of intended use

	4 Contact PNS System (Subject Device)	**Nalu Neurostimulation System (K183579) (Primary Predicate)**	**StimQ PNS System (K171366) (Reference Predicate)**	**StimQ PNS System (K152178) (Reference Device)**	**Medtronic Mattrix 3271/3272 (K934065) (Reference Device)**	**Medtronic Xtrel 3425 (K883780) (Reference Device)**	**Analysis of Technological Differences from Primary Predicate**
Individual Electrode length	3.0 mm	Same	Same	Same	Same	Same	Same
Electrode spacing	3.0 mm	4.0 mm	4.0 mm	4.0 mm	4.0 mm	4.0 mm	Differences do not affect safety and effectiveness of intended use
Electrode surface area	12.25 mm^2	12.25 mm^2	12.72 mm^2	12.72 mm^2	12.25 mm^2	12.25 mm^2	Same
Lead extension	Lead extension available	Lead extension available	NA	NA	Lead extension available	Lead extension available	Differences do not affect safety and effectiveness of intended use
Lead Anchor	Integrated Lead Tines	Separate molded silicone anchor with Ti locking mechanism	Integrated Lead Tines Separate Suture Sleeve Cap, Pellethane 55-D, placed over proximal end of stimulator	Suture Sleeve Cap, Pellethane 55-D, placed over proximal end of stimulator	Molded silicone anchor	Molded silicone anchor	Differences do not affect safety and effectiveness of intended use

Table: Substantial Equivalence Table - Therapy

	4 Contact PNS System (Subject Device)	**Nalu Neurostimulation System (K183579) (Predicate)**	**Analysis of Technological Differences**
Pulse Frequency	2 Hz to 1500 Hz	Same	Same
Pulse Width	12 µs to 1000 µs	Same	Same
Current/Voltage Regulated	Current	Same	Same
Output Voltage (300 Ohms)	0 to 3.1 V	Same	Same
Output Voltage (500 Ohms)	0 to 5.1 V	Same	Same
Output Voltage (800 Ohms)	0 to 8.2 V	Same	Same
Output Current (300 Ohms)	0 to 10.2 mA	Same	Same
Output Current (500 Ohms)	0 to 10.2 mA	Same	Same
Output Current (800 Ohms)	0 to 10.2 mA	Same	Same
Waveform	Charge balanced (delayed) biphasic asymmetrical	Same	Same
Pulse Shape	Decaying Exponential	Same	Same
Maximum phase charge (300 Ohms)	10.2 µC/pulse	Same	Same
Maximum phase charge (500 Ohms)	10.2 µC/pulse	Same	Same
Maximum phase charge (800 Ohms)	10.2 µC/pulse	Same	Same
Maximum charge density (300 Ohm)	83.3 $\mu C/cm^2$	Same	Same
Maximum charge density (500 Ohm)	83.3 $\mu C/cm^2$	Same	Same
Maximum charge density (800 Ohm)	83.3 $\mu C/cm^2$	Same	Same
Maximum current density (300 Ohm)	83.3 mA/cm^2	Same	Same
Maximum current density (500 Ohm)	83.3 mA/cm^2	Same	Same
Maximum current density (800 Ohm)	83.3 mA/cm^2	Same	Same
Net Charge	0 µC	Same	Same
Average Phase Power (300 Ohms)	0.031 W/phase	Same	Same
Average Phase Power (500 Ohms)	0.052 W/phase	Same	Same
Average Phase Power (800 Ohms)	0.083 W/phase	Same	Same
Average Phase Power density (300 Ohms)	0.25 W/cm^2/phase	Same	Same
Average Phase Power density (500 Ohms)	0.51 W/cm^2/phase	Same	Same

	4 Contact PNS System (Subject Device)	Nalu Neurostimulation System (K183579) (Predicate)	Analysis of Technological Differences
Average Phase Power density (800 Ohms)	0.55 W/cm^2/phase	Same	Same
Pulse Delivery Mode	Continuous	Same	Same
Current Path options	Bipolar	Same	Same
Software level of Concern	Moderate	Same	Same
Program Cycle	Cycle through programs	Same	Same
Pulse Pattern	Fine tuning of pulse patterns (On/Off; If On, spans from 12 µs to 1000 µs)	Same	Same
Dosage Time	Allows for stimulation to be applied in periodic doses (On/Off; If On, spans from 1 ms to 25 ms)	Same	Same
Transmit Frequency	40.68 MHz	Same	Same

All of the physical and therapeutic attributes for the 4 Contact PNS System are the same as the parameters in the predicate devices. There are no significant differences in these characteristics that would raise different questions of safety or effectiveness.

The main difference between the subject device and the primary predicate is the number and spacing of electrical contacts, integrated tines, and a coiled lead design. This reduced number of contacts reduces the stimulation area, allowing the physician to target a smaller affected area, if needed. The integrated tines eliminate the need for a separate anchor making the system more convenient to be placed in peripheral location. All of the physical attributes for the 4 Contact PNS System are within the parameters seen in the predicate and reference devices, or the differences are minor and do not affect the safe and effective use of the devices.

Nonclinical Performance Testing

Nalu Medical performed a range of testing to gather data supporting the safety and performance of the 4 Contact PNS System prior to use. Nalu follows the Design Controls section of 21 CFR 820.30, ISO 14971, and ISO 13485:2016. These procedures ensure that all designs are appropriately planned, defined, evaluated, transferred to production, and ongoing changes are reviewed for impact on safety and effectiveness and appropriately evaluated and tested. The system is designed and tested to ensure that it meets all applicable standards and guidance documents. Bench testing includes design verification and validation, sterilization validation, and biocompatibility testing. Human factors and usability testing were also performed on the device. Validation and performance testing demonstrate that the device meets user needs as reflected in the functional specification.

Applicable Standards and Guidance Documents

The testing for the 4 Contact PNS System includes the following test standards and guidance:

Table: Standards and Guidance Documents

Standard Number	Title
ISO 14708-1:2014	Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
ISO 14708-3:2017	Implants for surgery -- Active implantable medical devices -- Part 3: Implantable neurostimulators
IEC 62366-1:2015	Medical Devices – Part 1: Application of usability engineering to medical devices
ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 14971:2012 ISO 14971:2007	Medical devices -- Application of risk management to medical devices
ISO 11607-1:2006/Amd 1:2014 and -2:2006/Amd 1:2014	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems, Part 2: Validation requirements for forming, sealing and assembly processes
ISO 11135-1:2014	Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices
CISPR 11	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement
FDA Guidance: Applying Human Factors and Usability Engineering to Medical Devices issued February 3, 2016	

Biocompatibility testing

The biocompatibility testing followed the International Standard ISO 10993-1: 2009 "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process," as well as Guidance for Industry and Food and Drug Administration Staff Document entitled “Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,” issued on: June 16, 2016.

The same biocompatibility reports that supported the Nalu Neurostimulation System also support the 4 Contact PNS System in this submission. The materials and processes involved in producing the 4 Contact PNS System were already assessed in the previous test reports. No additional testing was necessary.

Animal Testing

Additional animal testing was not necessary to support the addition of the 4 Contact PNS System to this system.

Summary of Nonclinical Performance Testing

Verification testing of the 4 Contact PNS System included electrical and mechanical tests to show that the device met its target specifications over a range of operating and storage conditions. Validation, performance, and usability testing demonstrated that the device met user needs as reflected in the functional specification.

Clinical Performance Data

Nalu Medical determined that bench and non-clinical testing are sufficient to demonstrate that the 4 Contact PNS System is as safe and effective as the predicate device.

Conclusions

The bench and non-clinical data support the safety of the device, and the verification and validation demonstrated that the 4 Contact PNS System performs as intended in the specified use conditions. The results do not raise different questions of safety and effectiveness.