March 25, 2021

Nalu Medical, Inc.
Pauline Lieu
Principle Regulatory Affairs Associate
2320 Faraday Ave. Suite 100
Carlsbad, California 92008

Re: K203547
Trade/Device Name: Nalu Neurostimulation System
Regulation Number: 21 CFR 882.5880
Regulation Name: Implanted spinal cord stimulator for pain relief
Regulatory Class: Class II
Product Code: GZB, GZF
Dated: December 4, 2020
Received: December 4, 2020

Dear Pauline Lieu:

(NOTE: Reprocessed SUD device types require a separate attachment of the list of all models cleared in the submission. A corrected SE letter will be required if the attachment is omitted.)

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,

Jitendra Virani
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203547

Device Name
Nalu Neurostimulation System

Indications for Use *(Describe)*
For Spinal Cord Stimulation

This system is indicated as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain.
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.

For Peripheral Nerve Stimulation

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 day) 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

K203547

1. Submission Sponsor

Nalu Medical, Incorporated
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Phone: (858) 442-6370
Fax: (760) 448-2377
Contact Pauline Lieu, Ph.D.
Principle Regulatory Affairs Associate

Date Prepared: March 23rd, 2021

2. Device Names and Classification

Primary Product Code	
Proprietary Name	Nalu Neurostimulation System
Common Names	Stimulator, Spinal-Cord Implanted (Pain Relief);
Class	II
Classification Regulation	21 CFR 882.5880; Stimulator, Implanted Spinal-cord (Pain Relief)
Product Code	GZB
Review Panel	Division of Neurological and Physical Medicine Devices

Secondary Product Code	
Proprietary Name	Nalu Neurostimulation System
Common Names	Stimulator, Peripheral Nerve, Implanted (Pain Relief);
Class	II
Classification Regulation	21 CFR 882.5870 Stimulator, Peripheral Nerve Stimulator (Pain Relief)
Product Code	GZF
Review Panel	Division of Neurological and Physical Medicine Devices

3. Predicate and Reference Devices:

Predicate Device: Nalu Neurostimulation System (K201618)

Reference Devices: Medtronic Xtrel Model 3425 (K883780 and K982902)

4. Device Description

The Nalu Neurostimulation System has been cleared by the FDA for spinal cord stimulation, and peripheral nerve stimulation (K201618), to provide therapeutic relief for chronic, intractable pain of the trunk and/or limbs including unilateral, bilateral nerve pain. The Nalu Neurostimulation therapy utilizes pulsed electrical current to create an energy field that acts on nerves in the spinal cord or peripheral nerve to inhibit the transmission of pain signals to the brain. The Nalu System is implanted only following a successful trial period using the Nalu Neurostimulation trial system.

The Nalu Neurostimulation System consists of several components. The implantable pulse generator (IPG) provides electrical stimulation pulses that are transmitted through the leads, to the desired location, either on the spinal cord or peripheral nerve site. The leads are implantable and designed to deliver electrical pulses to the nerves via an array of four or eight cylindrical electrodes at the distal end. The Trial Therapy Disc or the Therapy Disc houses the battery and electronics for RF power and controls the IPG for therapy delivery via the remote programmer. Implantation of the Nalu IPG and lead components for spinal cord stimulation (SCS) or peripheral nerve stimulation (PNS) is performed via standard surgical tools and techniques, as described in (K201618).

5. Indications for Use

Spinal Cord Stimulation (SCS)

This system is indicated as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain.

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.

Peripheral Nerve Stimulation (PNS)

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.

6. Comparison with the Predicate and Reference Device:

The following tables illustrate the substantial equivalence between the subject, predicate, and reference devices.

Table 6.1. Primary Predicate and Reference Device Summary

	Nalu Neurostimulation System (Subject Device)	**Nalu Neurostimulation System (Predicate Device, K201618)**	**Medtronic Xtrel Model 3425 (Reference Device, K883780 and K982902)**	**Analysis of Technological Differences from Predicate**
510(k)	K203547	K201618 (SCS and PNS)	K883780 (SCS) K982902 (PNS)	NA
Product Code and class	GZB and GZF, Class II	GZB and GZF, Class II	GZB and GZF, Class II	Same
Regulation number	21 CFR 882.5880 (GZB) 21 CFR 882.5870 (GZF)	21 CFR 882.5880 (GZB) 21 CFR 882.5870 (GZF)	21 CFR 882.5880 (GZB) 21 CFR 882.5870 (GZF)	Same
Classification name	Implanted spinal cord stimulator for pain relief. (GZB) Implanted peripheral nerve stimulator for pain relief (GZF)	Same	Same	Same
Intended Use	Stimulation of spinal cord for chronic, intractable pain (GZB) Stimulation of peripheral nerves for chronic,	Same	Same	Same

	Nalu Neurostimulation System (Subject Device)	**Nalu Neurostimulation System (Predicate Device, K201618)**	**Medtronic Xtrel Model 3425 (Reference Device, K883780 and K982902)**	**Analysis of Technological Differences from Predicate**
	intractable pain (GZF)			
Indications for Use	SCS: The Nalu Neurostimulation System is indicated as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain. PNS: 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. Both SCS and PNS: The trial devices are solely used for trial stimulation (no longer than 30 days) to	Same	The X-trel Transmitter is part of a system for Spinal Cord Stimulation or Peripheral nerve Stimulation. The system is indicated in the management of chronic, intractable pain of the trunk or limbs	Same

	Nalu Neurostimulation System (Subject Device)	Nalu Neurostimulation System (Predicate Device, K201618)	Medtronic Xtrel Model 3425 (Reference Device, K883780 and K982902)	Analysis of Technological Differences from Predicate
	determine efficacy before recommendation for a permanent (long term) device.			
Prescription Use?	Yes	Same	Same	Same
Implant site, leads	Epidural space (SCS) or peripheral nerve areas (PNS)	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 produce stimulation at stimulator electrodes.	Same	Same	Same
Software Level of Concern	Moderate	Moderate	Unreported	Same

The Implanted Pulse Generator, Leads, all surgical implant accessories and all external accessories are unchanged from the predicate Nalu Neurostimulation System. The only difference between the subject devices and the predicate devices is the change in the software. The Nalu Neurostimulation System uses the same software for both SCS and PNS. A table below details the impact of those changes in comparison with the predicate and reference devices.

Table 6.2. Predicate and Reference Device comparison with the Nalu Neurostimulation therapy delivery

Comparator	Nalu Neurostimulation System (Subject Device)	Nalu Neurostimulation System (Predicate Device, K201618)	Medtronic Xtrel Model 3425 (Reference Device, K883780 and K982902)	Analysis of Technological Differences from Predicate
Pulse Frequency	2 Hz to 1500 Hz	2 Hz to 1500 Hz	5 to 1400 Hz	Same as predicate
Pulse Width	12 to 2000 µs	12 to 1000 µs	50 to 1000 µs	Available programmable pulse width will be capped to maintain Maximum Phase Charge and Maximum Charge Density within limits of Medtronic Xtrel reference device limit. No impact to safety and effectiveness.
Current/Voltage Regulated	Current	Same	Voltage	Same as predicate
Output Voltage (300 Ohms)	0 to 3.1 V	0 to 3.1 V	0 to 5.4 V	Same as predicate
Output Voltage (500 Ohms)	0 to 5.1 V	0 to 5.1 V	0 to 7.1 V	Same as predicate
Output Voltage (800 Ohms)	0 to 8.2 V	0 to 8.2 V	0 to 8.4 V	Same as predicate
Output Current (300 Ohms)	0 to 10.2 mA	0 to 10.2 mA	0 to 18.0 mA	Same as predicate
Output Current (500 Ohms)	0 to 10.2 mA	0 to 10.2 mA	0 to 14.2 mA	Same as predicate
Output Current (800 Ohms)	0 to 10.2 mA	0 to 10.2 mA	0 to 10.5 mA	Same as predicate

Comparator	Nalu Neurostimulation System (Subject Device)	Nalu Neurostimulation System (Predicate Device, K201618)	Medtronic Xtrel Model 3425 (Reference Device, K883780 and K982902)	Analysis of Technological Differences from Predicate
Waveform	charge balanced (delayed) biphasic asymmetrical	Same	Same	Same as predicate
Pulse Shape	Decaying Exponential	Same	Same	Same as predicate
Maximum phase charge (300 Ohms)	18.0 µC/pulse	10.2 µC/pulse	18.0 µC/pulse	Same as Medtronic Xtrel reference device
Maximum phase charge (500 Ohms)	18.0 µC/pulse	10.2 µC/pulse	14.2 µC/pulse	Same as Medtronic Xtrel reference device at 300 Ohms. Maximum Phase Charge constant in current controlled system and enforced below maximum reference device value (at 300 Ohms). No impact to safety and effectiveness.
Maximum phase charge (800 Ohms)	18.0 µC/pulse	10.2 µC/pulse	10.5 µC/pulse	Same as Medtronic Xtrel reference device at 300 Ohms. Maximum Phase Charge constant in current controlled system and enforced below maximum reference device value (at 300 Ohms). No impact to safety and effectiveness.
Maximum charge density (300 Ohm)	146.94 µC/cm^2	83.3 µC/cm^2	150.0 µC/cm^2	Within maximum limit as set by Medtronic Xtrel reference device.

Comparator	Nalu Neurostimulation System (Subject Device)	Nalu Neurostimulation System (Predicate Device, K201618)	Medtronic Xtrel Model 3425 (Reference Device, K883780 and K982902)	Analysis of Technological Differences from Predicate
Maximum charge density (500 Ohm)	146.94 µC/cm^2	83.3 µC/cm^2	118.3 µC/cm^2	Same as Medtronic Xtrel reference device at 300 Ohms. Maximum Phase Charge constant in current controlled system and enforced below maximum reference device value (at 300 Ohms). No impact to safety and effectiveness.
Maximum charge density (800 Ohm)	146.94 µC/cm^2	83.3 µC/cm^2	87.5 µC/cm^2	Same as Medtronic Xtrel reference device at 300 Ohms. Maximum Phase Charge constant in current controlled system and enforced below maximum reference device value (at 300 Ohms). No impact to safety and effectiveness.
Maximum current density (300 Ohm)	83.3 mA/cm^2	83.3 mA/cm^2	150.0 mA/cm^2	Same as predicate
Maximum current density (500 Ohm)	83.3 mA/cm^2	83.3 mA/cm^2	118.3 mA/cm^2	Same as predicate
Maximum current density (800 Ohm)	83.3 mA/cm^2	83.3 mA/cm^2	87.5 mA/cm^2	Same as predicate
Net Charge	0 µC	Same	Same	Same as predicate
Average Phase Power (300 Ohms)	0.031 W/phase	0.031 W/phase	0.068 W/phase	Same as predicate

Comparator	Nalu Neurostimulation System (Subject Device)	Nalu Neurostimulation System (Predicate Device, K201618)	Medtronic Xtrel Model 3425 (Reference Device, K883780 and K982902)	Analysis of Technological Differences from Predicate
Average Phase Power (500 Ohms)	0.052 W/phase	0.052 W/phase	0.074 W/phase	Same as predicate
Average Phase Power (800 Ohms)	0.083 W/phase	0.083 W/phase	0.066 W/phase	Same as predicate.
Average Phase Power density (300 Ohms)	0.25 W/cm^2/phase	0.25 W/cm^2/phase	0.57 W/cm^2/phase	Same as predicate.
Average Phase Power density (500 Ohms)	0.51 W/cm^2/phase	0.51 W/cm^2/phase	0.62 W/cm^2/phase	Same as predicate.
Average Phase Power density (800 Ohms)	0.55 W/cm^2/phase	0.55 W/cm^2/phase	0.55 W/cm^2/phase	Same as predicate.
Pulse Delivery Mode	Continuous	Same	Same	Same as predicate.
Current Path options	Bipolar	Same	Same	Same as predicate.
Program Cycle	Cycle through programs	Same	Details unavailable	Same as predicate.
Pulse Pattern	Fine tuning of pulse patterns (On/Off; If On, spans from 12 µs to 1000 µs)	Same	Details unavailable	Same as predicate.
Dosage Time	Allows for stimulation to be applied in periodic doses (On/Off; If On, spans from 1 ms to 1000 ms, If Off, spans from 1 ms to 2000 ms)	Allows for stimulation to be applied in periodic doses (On/Off; If On, spans from 1 ms to 25 ms)	Same (Cycle ON/OFF)	This parameter has no impact on safety and effectiveness considerations. Increasing the range allows the clinician to offer more flexibility to accommodate patient preferences

Comparator	Nalu Neurostimulation System (Subject Device)	Nalu Neurostimulation System (Predicate Device, K201618)	Medtronic Xtrel Model 3425 (Reference Device, K883780 and K982902)	Analysis of Technological Differences from Predicate
Daily Therapy Time	Limits the number of hours in a day that stimulation may be used (Seconds to hours)	Same	Details unavailable	Same as predicate.
Transmit Frequency	40.68 MHz	40.68 MHz	1.6 MHz	Same as predicate

7. Technological Characteristics

All of the physical and therapeutic attributes for the proposed Nalu Neurostimulation System and the predicate and reference devices share the same technological characteristics and have no differences that would impact safety or effectiveness.

8. Summary of Performance Testing

Nalu Medical performed a range of testing to gather data supporting the safety and performance of the Nalu Neurostimulation 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 evaluated and tested. The system is designed and tested to ensure that it meets all applicable standards and guidance documents. The subject device of this 510(k) has the same technological and performance criteria which have not changed from the predicate device. The proposed changes on the software specifications to increase therapy options are within the limits that have been previously cleared in predicate and reference devices. Validation and performance testing demonstrate that the device meets the performance criteria as reflected in the functional specifications. All of the required testing and results from the predicate device (K201618) remain applicable to the subject device of this 510(k) except for the updated software and firmware verification testing to support the proposed changes that are included in this submission.

9. Conclusions

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