July 15, 2020

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

Re: K201618
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: June 12, 2020
Received: June 15, 2020

Dear Pauline Lieu:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201618

Device Name
Nalu Neurostimulation System

Indications for Use *(Describe)*

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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K201618

Submission Sponsor

Nalu Medical, Incorporated
2320 Faraday Ave., Suite 100
Carlsbad, CA 92009
Phone: (760) 448-2360
Fax: (760) 448-2377
Contact Pauline Lieu, Regulatory Affairs

Date Prepared: June 12, 2020

Device Names and Classification

Predicate Device	
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

Reference Device	
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

Predicate Device

Nalu Neurostimulation System for Spinal Cord Stimulation (K183047)

Reference Devices: Nalu Neurostimulation System for Peripheral Nerve Stimulation (K183579 and K191435)

Device Description

The Nalu Neurostimulation system has been cleared by the FDA for spinal cord stimulation (SCS; K183047) and peripheral nerve stimulation (PNS; K183579, and K191435) 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 five 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 (K183047, K183579, and K191435).

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.

Comparison with the Predicate Device

Nalu Neurostimulation System for Spinal Cord Stimulation (SCS)

Device	Nalu Neurostimulation System (Predicate Device: K183047)	Nalu Neurostimulation System (Subject Device)	Analysis of Technological Differences
Trade Name	Nalu Neurostimulation System	Nalu Neurostimulation System	Same
Manufacturer	Nalu Medical, Inc.	Nalu Medical, Inc.	Same
Intended Use	The Nalu Neurostimulation system is intended for the stimulation of the spinal cord for treatment of chronic, intractable pain.	The Nalu Neurostimulation system is intended for the stimulation of the spinal cord for treatment of chronic, intractable pain.	Same
Indications for Use	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.	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.	Same
Clinical application	Treatment of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain	Treatment of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain	Same
Prescription Use	Yes	Yes	Same
Intended User	Physician, Layperson	Physician, Layperson	Same
Principle of Operation	Stimulation of the spinal cord to provide therapeutic relief for	Stimulation of the spinal cord to provide therapeutic relief for	Same

	chronic, intractable pain of the trunk and/or limbs including unilateral or bilateral pain	chronic, intractable pain of the trunk and/or limbs including unilateral or bilateral pain	
Mode of Action	RF wireless transmission of energy to deliver stimulation at stimulator electrodes	RF wireless transmission of energy to deliver stimulation at stimulator electrodes	Same
Implant Neurostimulator	Nalu IPG 27.7 mm x 9.3 mm x 4.2 mm	Nalu IPG 27.7 mm x 9.3 mm x 4.2 mm	Same
Lead	40 cm, 60 cm; Platinum-iridium 90:10; Multilumen tube	40 cm, 60 cm; Platinum-iridium 90:10; Multilumen tube	Same
Externally worn devices	Trial Therapy Disc and Therapy Disc	Trial Therapy Disc and Therapy Disc	Same
Electronics	A printed circuit board (PCB) that generates RF power with embedded waveform parameter settings and buttons for changing parameter settings	A printed circuit board (PCB) that generates RF power with embedded waveform parameter settings and buttons for changing parameter settings	Same
Clinician Programmer	Software to communicate to Trial Therapy or Therapy Disc	Software to communicate to Trial Therapy or Therapy Disc	Same
Patient Remote Control	Software to pair with Trial Therapy or Therapy Disc	Software to pair with Trial Therapy or Therapy Disc	Same
Human Factors	Integrated controls and indicators that allows the user to turn the device on/off, increase or decrease therapy levels, select from configured therapy profiles and monitor device status	Integrated controls and indicators that allows the user to turn the device on/off, increase or decrease therapy levels, select from configured therapy profiles and monitor device status	Same
Externally Contacting Materials	Hydrocolloid adhesive applied to skin Biocompatible PC ABS housing Textile material of belt	Hydrocolloid adhesive applied to skin Biocompatible PC ABS housing Textile material of belt	Same
Labeling	**Implantable Pulse Generator:** The service life of the Implantable Pulse Generator is 10 years.	**Implantable Pulse Generator:** The service life of the Implantable Pulse Generator is 18 years	New

	Therapy Disc: Single use	**Therapy Disc:** Re-usable	

Nalu Neurostimulation System for Peripheral Nerve Stimulation

Device	**Nalu Neurostimulation System (Reference Devices: K183579, K191435)**	**Nalu Neurostimulation System (Subject Device)**	**Analysis of Technological Differences**
Trade Name	Nalu Neurostimulation System	Nalu Neurostimulation System	Same
Manufacturer	Nalu Medical, Inc.	Nalu Medical, Inc.	Same
Intended Use	The Nalu Neurostimulation system is intended for the stimulation of the peripheral nerve for treatment of chronic, intractable pain.	The Nalu Neurostimulation system is intended for the stimulation of the peripheral nerve for treatment of chronic, intractable pain.	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 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.	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.	Same
Clinical application	Treatment of chronic peripheral nerve pain	Treatment of chronic peripheral nerve pain	Same
Prescription Use	Yes	Yes	Same
Intended User	Physician, Layperson	Physician, Layperson	Same

Device	Nalu Neurostimulation System (Reference Devices: K183579, K191435)	Nalu Neurostimulation System (Subject Device)	Analysis of Technological Differences
Principle of Operation	Stimulation of the peripheral nerve to provide therapeutic relief for chronic pain	Stimulation of the peripheral nerve to provide therapeutic relief for chronic pain	Same
Mode of Action	RF wireless transmission of energy to deliver stimulation at stimulator electrodes	RF wireless transmission of energy to deliver stimulation at stimulator electrodes	Same
Implant Neurostimulator	Nalu IPG 27.7 mm x 9.3 mm x 4.2 mm	Nalu IPG 27.7 mm x 9.3 mm x 4.2 mm	Same
Lead	40 cm, 60 cm; Platinum-iridium 90:10; Multilumen tube 25 cm, 40 cm Platinum-iridium 90:10, Coiled wires	40 cm, 60 cm; Platinum-iridium 90:10; Multilumen tube 25 cm, 40 cm Platinum-iridium 90:10, Coiled wires	Same
Externally worn devices	Trial Therapy Disc and Therapy Disc	Trial Therapy Disc and Therapy Disc	Same
Electronics	A printed circuit board (PCB) that generates RF power with embedded waveform parameter settings and buttons for changing parameter settings	A printed circuit board (PCB) that generates RF power with embedded waveform parameter settings and buttons for changing parameter settings	Same
Clinician Programmer	Software to communicate to Trial Therapy or Therapy Disc	Software to communicate to Trial Therapy or Therapy Disc	Same
Patient Remote Control	Software to pair with Trial Therapy or Therapy Disc	Software to pair with Trial Therapy or Therapy Disc	Same
Human Factors	Integrated controls and indicators that allows the user to turn the device on/off, increase or decrease therapy levels, select from configured therapy profiles and monitor device status	Integrated controls and indicators that allows the user to turn the device on/off, increase or decrease therapy levels, select from configured therapy profiles and monitor device status	Same
Externally Contacting Materials	Hydrocolloid adhesive applied to skin	Hydrocolloid adhesive applied to skin	Same

Device	Nalu Neurostimulation System (Reference Devices: K183579, K191435)	Nalu Neurostimulation System (Subject Device)	Analysis of Technological Differences
	Biocompatible PC ABS housing Textile material of belt	Biocompatible PC ABS housing Textile material of belt	
Labeling	**Implantable Pulse Generator:** The service life of the Implantable Pulse Generator is 10 years. **Therapy Disc:** Single use	**Implantable Pulse Generator:** The service life of the Implantable Pulse Generator is 18 years **Therapy Disc:** Re-usable	New

Technological Characteristics

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

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. The system is designed and tested to ensure that it meets all applicable standards and guidance documents. Validation and performance testing demonstrate that the device meets user needs as reflected in the functional specification. The subject device of this 510(k) has the same technological and performance criteria which have not changed from the predicate device. All relevant testing for the proposed labeling changes were submitted and cleared in the previous submissions (K183047, K183579, and K191435). Therefore, test results from the predicate device remain applicable to the subject device of this 510(k).

Conclusion

The subject device of this 510(k) is substantially equivalent to the predicate devices as they are identical with regard to indications for use, performance and the technological characteristics. Risk analysis of the proposed changes did not raise any questions of safety and effectiveness.