November 9, 2020

Nalu Medical, Inc.
Pauline Lieu, Ph.D.
Regulatory Affairs Consultant
2320 Faraday Ave. Suite 100
Carlsbad, California 92009

Re: K202274
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
Dated: August 10, 2020
Received: August 11, 2020

Dear Dr. 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,

Pamela D. 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)*
K202274

Device Name

Nalu Neurostimulation System for SCS

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.

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

K202274

1. Submission Sponsor

Nalu Medical, Incorporated
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Contact Pauline Lieu, Regulatory Affairs

Date Prepared: Aug. 10th, 2020

2. 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

3. Predicate Device:

Nalu Neurostimulation System for Spinal Cord Stimulation (K183047)

4. Device Description

The Nalu Neurostimulation system has been cleared by the FDA (K183047) for spinal cord stimulation to provide therapeutic relief for chronic, intractable pain of the trunk and/or

limbs including unilateral or bilateral pain. The Nalu Neurostimulation therapy utilizes pulsed electrical current to create an energy field that acts on nerves in the spinal cord 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 is consisted of five components. The implantable pulse generator (IPG) provides electrical stimulation pulses that are transmitted through the leads, through the dura, to the desired location of the spinal cord site. The leads are implantable and designed to deliver electrical pulses to the spinal cord in the epidural space via an array of eight cylindrical electrodes at the distal end. The leads may be secured in place with the Nalu Lead Anchor. 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) is performed via standard SCS surgical tools and techniques, as described in (K183047).

The Nalu Neurostimulation System has been previously cleared by the FDA (K183047) with the magnetic resonance imaging (MRI) Conditional Labeling for the leads, anchor and implantable pulse generator which can be scanned safely with the local RF coils, including head, foot/ankle, knee, or wrist, as stated in the instructions for use. In this submission, Nalu performed MRI testing on the standard horizontal MR bore system to support the safety of the RF body coil. Nalu proposes an update to the MR Conditional Labeling with the full body scan as indicated in the proposed labeling update.

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.

6. Comparison with the Predicate Device:

Table 1. **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 chronic, intractable pain of the trunk and/or limbs including unilateral or bilateral pain	Stimulation of the spinal cord to provide therapeutic relief for chronic, intractable pain of the trunk and/or limbs including unilateral or bilateral 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	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	Clip adhesives applied to skin Biocompatible PC ABS housing	Clip adhesives applied to skin Biocompatible PC ABS housing	Same

	Textile material of belt	Textile material of belt	
Labeling	MR Conditional Labeling for Head and Extremities Full Body Do not use RF transmit body coil	MR Conditional Labeling for Head and Extremities Full body MR Conditional Labeling for Full Body	Same Different but does not raise different questions of safety and effectiveness

7. Technological Characteristics

All of the physical and therapeutic attributes for the proposed Nalu Neurostimulation System and the predicate device (K183047) share the same technological characteristics and has no differences that would impact safety or effectiveness.

8. Summary of nonclinical 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. Bench testing includes design verification and validation, sterilization validation, and biocompatibility testing. Human factors and usability testing were performed on the device. 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. Therefore, test results from the predicate device (K183047) except for the updated Magnetic Resonance testing remain applicable to the subject device of this 510(k).

Table 2. Applicable Standards and Guidance Documents

The testing for the labeling changes proposed for the Nalu Neurostimulation System includes the following test standards and guidance:

Standard Number	Title
ISO/TS 10974	Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device
ISO 14708	Implant for surgery – Active implantable medical devices – Part 1 and Part 3, General requirements and Implantable neurostimulator

ASTM F2052-15	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
ASTM F2213-17	Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
ASTM F2129-2013	Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants

9. Clinical performance data

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

10. Conclusions

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. Nalu performed testing to support the full body MR scan and the proposed changes in the instructions for use to ensure the safety and effectiveness of the device.