August 21, 2024

Nalu Medical, Inc.
Chelsea Gutierrez
Vice President, Quality Assurance and Regulatory Affairs
2320 Faraday Ave. Suite 100
Carlsbad, California 92008

Re: K232415
Trade/Device Name: Nalu Neurostimulation Kit (Integrated 40 cm: Single 8/Dual 8), Nalu Neurostimulation Kit (Ported, 2 cm: Single 8/Dual 8), Dual 8 Ported Nalu Implantable Pulse Generator with 40 cm Kit, 40cm/60cm/ 60cm Trial/ Extension Lead Kits, Patient Kits and Miscellaneous Replacement Kits
Regulation Number: 21 CFR 882.5870
Regulation Name: Implanted Peripheral Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: GZF
Dated: April 24, 2024
Received: April 24, 2024

Dear Chelsea Gutierrez:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lauren E. Woodard -S

for Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation and

Rehabilitation 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)*
K232415

Device Name
Nalu Neurostimulation System for Peripheral Nerve Stimulation

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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Submission Sponsor

Nalu Medical, Inc.
2320 Faraday Avenue, Suite 100
Carlsbad, CA 92008
Phone: (760) 448-2360
Fax: (760) 448-2377
Contact: Chelsea Gutierrez, Vice President of Regulatory Affairs and Quality Assurance

Date Prepared: May 15, 2024

Device Names and Classification

Device Identification	
510(k) Number	*K232415*
Trade/Proprietary Name	*Nalu Neurostimulation System for Peripheral Nerve Stimulation*
Common/Usual Name	*Peripheral Nerve Stimulator*
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*
Neurology	*Neurology*

Predicate/Reference Devices

- Predicate Device: Nalu Neurostimulation System for Peripheral Nerve Stimulation (K183579)
- Reference Device: Nalu Neurostimulation System, 4 Contact PNS System (K191435)
- Reference Device: Nalu Neurostimulation System for Spinal Cord Stimulation (K202274)

Device Description

The Nalu Neurostimulation System for Peripheral Nerve Stimulation (also referred to as the "Nalu System") is used for peripheral nerve stimulation to provide therapeutic relief for chronic, intractable pain of peripheral nerve origin. The Nalu System incorporates a miniature implantable pulse generator, 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 System may be implanted following a successful trial period using the Nalu Neurostimulation trial system. The Nalu System is comprised of 5 elements:

1. Nalu Implantable Pulse Generator	The implantable pulse generator (IPG), also referred to as the Implantable Neurostimulator (INS), 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 pre-attached leads and a "ported" system where leads may be attached, via connector ports. In addition, both of these versions are available in single or dual lead configurations. 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. Leads	Leads are implantable and are designed to deliver electrical pulses to the peripheral nerve via an array of eight cylindrical electrodes at the distal end. Leads may be integrated with or connected to the IPG. Both Trial and Permanent Implant leads are available for use. The leads use polyurethane insulation with Pt/Ir electrodes. The leads may be secured in place with the Nalu Lead Anchor.
3. Surgical and Trial Tools	Implantation of the Nalu IPG and lead components for Peripheral Nerve Stimulation (PNS) is performed via standard PNS surgical techniques. The desired implant location is accessed via needle placement, followed by lead placement through an introducer. The leads are anchored and the IPG is placed in a subcutaneous pocket. Patient contacting materials include medical grade stainless steel, thermoplastic elastomers, ABS, silicone, and Urethane.
4. Externally worn Therapy Disc	Two types of Therapy Disc are available, which are also referred to as the External Trial Stimulator (ETS) and the External Transmitter Module (ETM). One is to be used during the trial phase (Trial Therapy Disc or ETS), and one is to be used after permanent IPG implantation (Therapy Disc or ETM). Both devices are worn by the patient using one of the Nalu-provided options. The Therapy Discs house a rechargeable lithium-ion battery, and electronics including a microcontroller running software for therapy control, patient interaction and communication with Nalu's Clinician Programmer and Remote Control devices. The Therapy Disc used to power and command the implant does so wirelessly using Radio Frequency (RF) and is held in place by an adhesive clip applied to the skin or a belt/cuff worn over clothing.
5. Clinician Programmer and Remote Control	A Clinician Programmer Application is provided to configure the Trial Therapy Disc and Therapy Disc devices during surgery and programming. A Patient Remote Control Application is available to provide the patient with a convenient secondary option to control their system in addition to built-in controls on the Therapy Disc. The Clinician Programming Application runs on an Android tablet and communicates over a secure Bluetooth Low Energy link with the Trial Therapy Disc and Therapy Disc devices. The programmer is responsible for configuring the devices to deliver therapy according to clinician defined levels and patient preferences, and for managing patient and session records. The Patient Remote Control Application runs on iOS and Android platforms and offers basic control of the Trial Therapy Disc and Therapy Disc through a secure Bluetooth Low Energy link. The controls include selecting between clinician-defined therapy options (programs), turning stimulation on and off, and managing alerts.

The Nalu System has been previously cleared (K183579) by the FDA 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.

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.

Substantial Equivalence Comparison

The Indications for Use for the predicate device and subject device are identical. Any differences in the specifications or performance between the devices do not raise any different questions of safety or effectiveness, as demonstrated by performance testing. Thus, the subject device is substantially equivalent to the predicate device.

Testing results included in this submission support the full body MR Conditional Labeling proposed in the instructions for use. There are no other significant differences from the predicate device in these characteristics that would raise different questions of safety or effectiveness.

The following tables compare the Nalu 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. Please refer to Table 1 for Substantial Equivalence Table – General and Implanted Components, Table 2 for Substantial Equivalence Table – External Components and Table 3 for Substantial Equivalence Table – Clinician Programmer and Remote Control.

Table 1: Substantial Equivalence Table – General and Implanted Components

Substantial Equivalence Table – General and Implanted Components			
Device	**Nalu Neurostimulation System for Peripheral Nerve Stimulation (Subject Device)**	**Nalu Neurostimulation System for Peripheral Nerve Stimulation (Predicate Device)**	**Analysis of Technological Differences**
510(k)	K232415	K183579	Different.
Product Code and Class	GZF, Class II	GZF, Class II	Same as predicate.
Regulation Number	21 CFR §882.5870	21 CFR §882.5870	Same as predicate.
Classification Name	Implanted peripheral nerve stimulator for pain relief.	Implanted peripheral nerve stimulator for pain relief.	Same as predicate.
Intended Use	Stimulation of peripheral nerves for chronic, intractable pain	Stimulation of peripheral nerves for chronic, intractable pain	Same as predicate.
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 as predicate.
Prescription Use	Yes	Yes	Same as predicate.
Implant Site	Peripheral nerves, excluding craniofacial region	Peripheral nerves, excluding craniofacial region	Same as predicate.
Environmental Use	Hospital, Home	Hospital, Home	Same as predicate.
Intended Clinician	Orthopedic, Neurosurgeon, Anesthesiologist	Orthopedic, Neurosurgeon, Anesthesiologist	Same as predicate.
Intended User	Physician, Layperson	Physician, Layperson	Same as predicate.
Mode of Action	Radiofrequency (RF) wireless transmission of energy to produce stimulation at stimulator electrodes.	Radiofrequency (RF) wireless transmission of energy to produce stimulation at stimulator electrodes.	Same as predicate.
Labeling	MR Conditional Labeling for Head and Extremities Full Body MR Conditional Labeling for Full Body	MR Conditional Labeling for Head and Extremities Full Body Do not use RF transmit body coil	Different than predicate. Testing included in this submission demonstrates the safety and compatibility of the

Table 1: Substantial Equivalence Table – General and Implanted Components

Substantial Equivalence Table – General and Implanted Components			
Device	**Nalu Neurostimulation System for Peripheral Nerve Stimulation (Subject Device)**	**Nalu Neurostimulation System for Peripheral Nerve Stimulation (Predicate Device)**	**Analysis of Technological Differences**
			Nalu System for PNS in the Magnetic Resonance (MR) Environment for full body.
IPG			
Dimensions	Lead = 1.30 mm diameter IPG = 28 x 11 x 4.9 mm	Lead = 1.30 mm diameter IPG = 28 x 11 x 4.9 mm	Same as predicate.
Housing Material	Silicone and Pellethane 2363-55D	Silicone and Pellethane 2363-55D	Same as predicate.
Implant Site	Peripheral nerves, excluding craniofacial region	Peripheral nerves, excluding craniofacial region	Same as predicate.
Electrical Components	Embedded receiver, flexible circuit board	Embedded receiver, flexible circuit board	Same as predicate.
Power Delivery	Coupled receiver radio frequency transmission	Coupled receiver radio frequency transmission	Same as predicate.
Lead			
Electrode Material	Platinum-iridium 90:10	Platinum-iridium 90:10	Same as predicate.
Insulation Body Material	Pellethane 2363-55D	Pellethane 2363-55D	Same as predicate.
Cable Features	Multilumen tube	Multilumen tube	Same as predicate.
Lead Length	40 cm, 60 cm	40 cm, 60 cm	Same as predicate.
Diameter	1.30 mm	1.30 mm	Same as predicate.
Electrode Array Length	52 mm	52 mm	Same as predicate.
No. of Electrodes (per lead)	8	8	Same as predicate.
Individual Electrode Length	3.0 mm	3.0 mm	Same as predicate.
Electrode Spacing	4.0 mm	4.0 mm	Same as predicate.
Electrode Surface Area	12.25 mm^2	12.25 mm^2	Same as predicate.

Table 1: Substantial Equivalence Table – General and Implanted Components

Substantial Equivalence Table – General and Implanted Components			
Device	**Nalu Neurostimulation System for Peripheral Nerve Stimulation (Subject Device)**	**Nalu Neurostimulation System for Peripheral Nerve Stimulation (Predicate Device)**	**Analysis of Technological Differences**
Lead Extension	Lead extension available	Lead extension available	Same as predicate.
Lead Anchor	Molded silicone anchor with Ti locking mechanism	Molded silicone anchor with Ti locking mechanism	Same as predicate.
Configurations	Integrated and with Ports	Integrated and with Ports	Same as predicate.
Sterilization	Ethylene Oxide	Ethylene Oxide	Same as predicate.

Table 2: Substantial Equivalence Table – External Components

Substantial Equivalence Table – External Components			
Device	**Nalu Neurostimulation System (Subject Device)**	**Nalu Neurostimulation System for PNS (Predicate Device)**	**Analysis of Technological Differences**
Name	Therapy Disc and Trial Therapy Disc	Therapy Disc and Trial Therapy Disc	Same as predicate.
Electronics	A printed circuit board (PCB) that generates RF power with embedded waveform parameter settings and buttons for changing parameter settings as needed by the user	A printed circuit board (PCB) that generates RF power with embedded waveform parameter settings and buttons for changing parameter settings as needed by the user	Same as predicate.
User Interface	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 as predicate.
Antenna (Therapy Disc only)	Integrated antenna supporting 40.68 MHz power and data transfer.	Integrated antenna supporting 40.68 MHz power and data transfer.	Same as predicate.
Wearing (Therapy Disc only)	Therapy Disc is positioned over Nalu IPG via two options: • Adhesive clip (hydrocolloid adhesive) • Elastic Belt/Cuff	Therapy Disc is positioned over Nalu IPG via two options: • Adhesive clip (hydrocolloid adhesive) • Elastic Belt/Cuff	Same as predicate.
Size/Weight	Disc: ~1. 5 cm thick, 7. 5 cm diameter Weight: ~0.08 kg	Disc: ~1. 5 cm thick, 7. 5 cm diameter Weight: ~0.08 kg	Same as predicate.
Externally contacting Materials	Biocompatible PC ABS housing. Occasional contact to fingers (e.g., button use). Textile material of belt/cuff may be worn over clothing. Hydrocolloid adhesive applied to skin.	Biocompatible PC ABS housing. Occasional contact to fingers (e.g., button use). Textile material of belt/cuff may be worn over clothing. Hydrocolloid adhesive applied to skin.	Same as predicate.

Table 2: Substantial Equivalence Table – External Components

Substantial Equivalence Table – External Components			
Device	**Nalu Neurostimulation System (Subject Device)**	**Nalu Neurostimulation System for PNS (Predicate Device)**	**Analysis of Technological Differences**
Battery Charging	Electrically isolated cradle charger	Electrically isolated cradle charger	Same as predicate.

Table 3: Substantial Equivalence Table – Clinician Programmer and Remote Control

Substantial Equivalence Table – Clinician Programmer and Remote Control			
Device	**Nalu Neurostimulation System (Subject Device)**	**Nalu Neurostimulation System for PNS (Predicate Device)**	**Analysis of Technological Differences**
Clinician Programmer			
Configuration	Software installed on a compatible Android tablet.	Software installed on a compatible Android tablet.	Same as predicate.
Purpose	Allows healthcare provider to set desired therapy levels and device settings across Therapy Disc, Trial Therapy Disc, and Patient Remote Control devices.	Allows healthcare provider to set desired therapy levels and device settings across Therapy Disc, Trial Therapy Disc, and Patient Remote Control devices.	Same as predicate.
Communication	Secure Bluetooth to Therapy Disc, Trial Therapy Disc, and Patient Remote Control.	Secure Bluetooth to Therapy Disc, Trial Therapy Disc, and Patient Remote Control.	Same as predicate.
Patient Remote Control			
Patient Remote Control	Software app installed on compatible mobile device (Android/iOS) providing wireless selection among preconfigured options and status readout for paired Therapy Disc and Trial Therapy Disc devices.	Software app installed on compatible mobile device (Android/iOS) providing wireless selection among preconfigured options and status readout for paired Therapy Disc and Trial Therapy Disc devices.	Same as predicate.

Table 4: Substantial Equivalence Table – Therapy

Substantial Equivalence Table - Therapy			
Device	**Nalu Neurostimulation System (Subject Device)**	**Nalu Neurostimulation System for PNS (Predicate Device)**	**Analysis of Technological Differences**
Pulse Frequency	2 Hz to 1500 Hz	2 Hz to 1500 Hz	Same as predicate.
Pulse Width	12 to 2000 µs	12 to 1000 µs	No impact to therapy. Programming changes were made as part of the software update (cleared under K203547).
Current/Voltage Regulated	Current	Current	Same as predicate.
Output Voltage (300 Ohms)	0 to 3.1 V	0 to 3.1 V	Same as predicate.
Output Voltage (500 Ohms)	0 to 5.1 V	0 to 5.1 V	Same as predicate.

Substantial Equivalence Table - Therapy			
Device	**Nalu Neurostimulation System (Subject Device)**	**Nalu Neurostimulation System for PNS (Predicate Device)**	**Analysis of Technological Differences**
Output Voltage (800 Ohms)	0 to 8.2 V	0 to 8.2 V	Same as predicate.
Output Current (300 Ohms)	0 to 10.2 mA	0 to 10.2 mA	Same as predicate.
Output Current (500 Ohms)	0 to 10.2 mA	0 to 10.2 mA	Same as predicate.
Output Current (800 Ohms)	0 to 10.2 mA	0 to 10.2 mA	Same as predicate.
Waveform	charge balanced (delayed) biphasic asymmetrical	charge balanced (delayed) biphasic asymmetrical	Same as predicate.
Pulse Shape	Decaying Exponential	Decaying Exponential	Same as predicate.
Maximum phase charge (300 Ohms)	10.2 µC/pulse	10.2 µC/pulse	Same as predicate.
Maximum phase charge (500 Ohms)	10.2 µC/pulse	10.2 µC/pulse	Same as predicate.
Maximum phase charge (800 Ohms)	10.2 µC/pulse	10.2 µC/pulse	Same as predicate.
Maximum charge density (300 Ohm)	83.3 µC/cm^2	83.3 µC/cm^2	Same as predicate.
Maximum charge density (500 Ohm)	83.3 µC/cm^2	83.3 µC/cm^2	Same as predicate.
Maximum charge density (800 Ohm)	83.3 µC/cm^2	83.3 µC/cm^2	Same as predicate.
Maximum current density (300 Ohm)	83.3 mA/cm^2	83.3 mA/cm^2	Same as predicate.
Maximum current density (500 Ohm)	83.3 mA/cm^2	83.3 mA/cm^2	Same as predicate.
Maximum current density (800 Ohm)	83.3 mA/cm^2	83.3 mA/cm^2	Same as predicate.
Net Charge	0 uC	0 uC	Same as predicate.
Average Phase Power (300 Ohms)	0.031 W/phase	0.031 W/phase	Same as predicate.
Average Phase Power (500 Ohms)	0.052 W/phase	0.052 W/phase	Same as predicate.
Average Phase Power (800 Ohms)	0.083 W/phase	0.083 W/phase	Same as predicate.
Average Phase	0.25 W/cm^2/phase	0.25 W/cm^2/phase	Same as

Substantial Equivalence Table - Therapy			
Device	**Nalu Neurostimulation System (Subject Device)**	**Nalu Neurostimulation System for PNS (Predicate Device)**	**Analysis of Technological Differences**
Power density (300 Ohms)			predicate.
Average Phase Power density (500 Ohms)	0.51 W/cm^2/phase	0.51 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	Same as predicate.
Pulse Delivery Mode	Continuous	Continuous	Same as predicate.
Current Path options	Bipolar	Bipolar	Same as predicate.
Program Cycle	Cycle through programs	Cycle through programs	Same as predicate.
Pulse Pattern (advanced programming)	Fine tuning of pulse patterns (On/Off; If On, spans from 12 µs to 1000 µs)	Fine tuning of pulse patterns (On/Off; If On, spans from 12 µs to 1000 µs)	Same as predicate.
Dosage Time (advanced programming)	Allows for stimulation to be applied in periodic doses (On/Off; If On, spans from 1 ms to 25 ms)	Allows for stimulation to be applied in periodic doses (On/Off; If On, spans from 1 ms to 25 ms)	Same as predicate.
Daily Therapy Time	Limits the number of hours in a day that stimulation may be used (Seconds to hours)	Limits the number of hours in a day that stimulation may be used (Seconds to hours)	Same as predicate.
Transmit Frequency	40.68 MHz	40.68 MHz	Same as predicate.

Technological Characteristics

The subject device and the predicate device (K183579) share the same technological characteristics with regard to physical and therapeutic attributes. There are no differences that would impact safety or effectiveness.

Summary of Non-Clinical Performance Testing

Nalu Medical performed a range of testing to gather data supporting the safety and performance of the Nalu 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 Nalu 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 (K183579) except for the updated Magnetic Resonance testing remain applicable to the subject device of this 510(k).

The testing for the labeling changes proposed for the Nalu System includes the following test standards.

Table 5. Applicable Standards

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 F2119-2013	Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants

Clinical Performance Data

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

Conclusion

The subject device of this 510(k) is substantially equivalent to the predicate device 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 were made to ensure the safety and effectiveness of the device.