March 22, 2019

Nalu Medical, Inc
Michele Chin-Purcell
Vice President RA/QA
1525 Faraday Ave. Suite 180
Carlsbad, California 92008

Re: K183047
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: February 17, 2019
Received: February 21, 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K183047

Device Name
Nalu Neurostimulation System

Indications for Use *(Describe)*
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.

The trial devices are solely used for trial stimulation (no longer thank 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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5.1. Submission Sponsor

Nalu Medical, Incorporated
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Carlsbad, CA 92009
Phone: (760) 448-2360
Fax: (760) 448-2377
Contact: Michele Chin-Purcell, Vice President of Regulatory Affairs and Quality Assurance

5.2. Date Prepared

March 20, 2019

5.3. Device Identification

Trade/Proprietary Name: Nalu Neurostimulation System
Common/Usual Name: Spinal Cord Stimulator
Product Code: GZB
Regulation number: 21 CFR 882.5880: Stimulator, spinal-cord, implanted (Pain Relief)
Class: Class II
Device Classification Panel: Neurology

5.4. Legally Marketed Predicate Device(s)

Freedom SCS System (K170141) by Stimwave Technologies, Inc.
Hereafter, also referred to as the Stimwave Freedom SCS System.

In addition, references are made to other 510(k) devices that were used as part of the predicate history to the primary predicate in this submission. This history of the predicates is summarized in **Table 5-1**:

Table 5-1: Predicate history of the proposed primary predicate

Device	510(k)	Predicate(s) used for clearance
Stimwave Freedom SCS System	K141399	Medtronic Mattrix 3271/3272 (K934065) Medtronic Xtrel, 3425 (K883780) ANS Renew (K000852)
Stimwave Freedom SCS System	K150517	K141399
Stimwave Freedom SCS System	K160600	K150517
Stimwave Freedom SCS System	K162161	K160600

Stimwave Freedom SCS System (Primary Predicate)	K170141	K162161

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

5.5. **Device Description**

The Nalu Neurostimulation system (also referred to as the "Nalu System") is used 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 system incorporates a miniature implanted neurostimulator, powered by an externally worn device. Similar to the predicate Stimwave system, 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 comprised of 5 elements:

1. Nalu Implantable Pulse Generator	The implantable pulse generator (IPG) provides electrical stimulation pulses that are transmitted through the leads, through the dura, to the desired spinal cord site. 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 spinal cord in the epidural space 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 Spinal Cord Stimulation (SCS) is performed via standard SCS surgical techniques. Epidural space is accessed via epidural needle placement with the loss of resistance technique, 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 Discs	Two types of Therapy Disc are available. One is to be used during the trial phase (Trial Therapy Disc), and one is to be used after permanent IPG implantation (Therapy Disc). Both devices are worn by the patient using one of 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 worn against the skin or over clothing.
5. Programmer, Remote	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 issued to provide the patient with a convenient secondary option to control their system in addition to the 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 physician-defined therapy options, turning stimulation on and off, and managing alerts.

5.6. Indications for Use Statement

"The 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."

The Indications for Use statement for the Nalu Neurostimulation System is not identical to the predicate device; however, the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the

predicate. Both the subject and predicate devices have the same intended use for the stimulation of the spinal cord for treatment of chronic, intractable pain.

5.7. Substantial Equivalence Discussion

The following tables compare the Nalu Neurostimulation 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 5-2: Substantial Equivalence Table – General and Implanted Components

	Nalu Neurostimulation System (Subject Device)	**Stimwave Freedom-8 SCS system (Primary Predicate)**	**Stimwave Freedom SCS system (Reference Device)**	**Medtronic Mattrix 3271/3272 (Reference Device)**	**Medtronic Xtrel 3425 (Reference Device)**	**ANS Renew (Reference Device)**	**Analysis of Technological Differences from Primary Predicate**
510(k)	TBD	K170141	K141399	K934065	K883780	K000852	NA
Product Code and class	GZB, Class II	Same	Same	Same	Same	Same	Same
Regulation number	21 CFR 882.5880	Same	Same	Same	Same	Same	Same
Classification name	Implanted spinal cord stimulator for pain relief.	Same	Same	Same	Same	Same	Same
Intended Use	Stimulation of spinal cord for chronic, intractable pain	Same	Same	Same	Same	Same	Same
Indications for Use	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,	The Freedom Spinal Cord Stimulator (SCS) System is intended 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 lower limbs, including unilateral or bilateral pain. The Freedom-8A Trial Lead Kit is only used in conjunction with the Freedom-8A Stimulator Receiver Kit, and the Freedom-4A Trial Lead Kit is used for either the Receiver Kit Freedom-4A Stimulator or the Receiver Kit Freedom-		Indicated as an aide in the management of chronic, intractable pain of the trunk or limbs		Indicated for the treatment of chronic pain of trunk and limbs, either as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach.	Differences do not affect safety and effectiveness of intended use

	Nalu Neurostimulation System (Subject Device)	**Stimwave Freedom-8 SCS system (Primary Predicate)**	**Stimwave Freedom SCS system (Reference Device)**	**Medtronic Mattrix 3271/3272 (Reference Device)**	**Medtronic Xtrel 3425 (Reference Device)**	**ANS Renew (Reference Device)**	**Analysis of Technological Differences from Primary Predicate**
	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.	8A Stimulator. 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
Anatomical site	Epidural space	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

	Nalu Neurostimulation System (Subject Device)	**Stimwave Freedom-8 SCS system (Primary Predicate)**	**Stimwave Freedom SCS system (Reference Device)**	**Medtronic Mattrix 3271/3272 (Reference Device)**	**Medtronic Xtrel 3425 (Reference Device)**	**ANS Renew (Reference Device)**	**Analysis of Technological Differences from Primary Predicate**
Software Level of Concern	Moderate	Moderate	Moderate	Unreported	Unreported	Moderate	Same

	Nalu Neurostimulation System (Subject Device)	**Stimwave Freedom SCS system (K170141) (Primary Predicate)**	**Stimwave Freedom SCS system (K141399) (Reference Device)**	**Medtronic Mattrix 3271/3272 (K934065) (Reference Device)**	**Medtronic Xtrel 3425 (K883780) (Reference Device)**	**ANS Renew (K000852)**	**Analysis of Technological Differences from Primary Predicate**
IPG							
Dimensions	Lead = 1.30 mm diameter IPG = 28 x 11 x 4.9 mm	Integrated with lead body, 1.35 mm diameter	Integrated with lead body, 1.35 mm diameter	Details unavailable			Differences do not affect safety and effectiveness of intended use
Housing material	Silicone and Pellethane 2363-55D	Pellethane 2363-55D	Pellethane 2363-55D	Details unavailable.			Differences do not affect safety and effectiveness of intended use
Implant location	Lead: Epidural space IPG: Subcutaneous, mid back	Epidural space and Subcutaneous, mid back	Same	Same	Same	Same	Same
Electrical components	Embedded receiver, flexible circuit board	Same	Same	Sealed electronic circuits	Sealed electronic circuits	Sealed electronic circuits	Same
Power Delivery	Coupled receiver radio frequency transmission	Same	Same	Same	Same	Coupled receiver, hardwired	Same

	Nalu Neurostimulation System (Subject Device)	**Stimwave Freedom SCS system (K170141) (Primary Predicate)**	**Stimwave Freedom SCS system (K141399) (Reference Device)**	**Medtronic Mattrix 3271/3272 (K934065) (Reference Device)**	**Medtronic Xtrel 3425 (K883780) (Reference Device)**	**ANS Renew (K000852)**	**Analysis of Technological Differences from Primary Predicate**
						with connector	
Lead							
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	Multilumen tube	Same	Same	Coiled Wires	Coiled Wires	Braided Wire	Same
Lead length	40 cm, 60 cm	44 cm	45 cm	30 to 110 cm	30 to 110 cm	30 and 60 cm	Differences do not affect safety and effectiveness of intended use
Diameter	1.30 mm	1.35 mm	1.35 mm	1.3 mm	1.3 mm	1.37 mm	Differences do not affect safety and effectiveness of intended use
Electrode Array length	52 mm	24 mm (FRE-4) 52 mm (FRE-8)	24 mm	24 mm	24 mm	24 mm	Differences do not affect safety and effectiveness of intended use
No. of Electrodes, per lead	8	4 (FRE-4) 8 (FRE-8)	4	Same	Same	4 or 8	Differences do not affect safety and effectiveness of intended use
Individual Electrode length	3.0 mm	Same	Same	Same	Same	Same	Same

	Nalu Neurostimulation System (Subject Device)	**Stimwave Freedom SCS system (K170141) (Primary Predicate)**	**Stimwave Freedom SCS system (K141399) (Reference Device)**	**Medtronic Mattrix 3271/3272 (K934065) (Reference Device)**	**Medtronic Xtrel 3425 (K883780) (Reference Device)**	**ANS Renew (K000852)**	**Analysis of Technological Differences from Primary Predicate**
Electrode spacing	4.0 mm	Same	Same	Same	Same	Same	Same
Electrode surface area	12.25 mm^2	12.72 mm^2	12.72 mm^2	12.25 mm^2	12.25 mm^2	~13 mm^2	Differences do not affect safety and effectiveness of intended use
Lead extension	Lead extension available	NA	NA	Lead extension available	Lead extension available	Lead extension available	Differences do not affect safety and effectiveness of intended use
Lead Anchor	Molded silicone anchor with Ti locking mechanism	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	Molded silicone anchor	Differences do not affect safety and effectiveness of intended use
Configurations	Integrated and with Ports	Integrated	Integrated	With Ports	With Ports	With Ports	Differences do not affect safety and effectiveness of intended use
Sterilization	Ethylene Oxide	Same	Same	Same	Same	Same	Same

Table 5-3: Substantial Equivalence Table - Therapy

Comparator	Nalu Neurostimulation System (Subject Device)	Stimwave Freedom SCS system (K170141) (Primary Predicate)	Stimwave Freedom SCS system (K141399) (Reference Device)	Medtronic Mattrix 3271/3272 (K934065) (Reference Device)	Medtronic Xtrel 3425 (K883780) (Reference Device)	ANS Renew (K000852) (Reference Device)	Analysis of Technological Differences from Primary Predicate
Pulse Frequency	2 Hz to 1500 Hz	5 to 1500 Hz	2 Hz to 1500 Hz	5 to 240 Hz	5 to 1400 Hz	10 to 1500 Hz	Differences do not affect safety and effectiveness of intended use
Pulse Width	12 to 1000 µs	49 to 500 µs	50 to 500 µs	50 to 500 µs	50 to 1000 µs	50 to 500 µs	Differences do not affect safety and effectiveness of intended use
Current/Voltage Regulated	Current	Current	Current	Voltage	Voltage	Current	Same
Output Voltage (300 Ohms)	0 to 3.1 V	0 to 4.1 V	0 to 6.3 V	0 to 7 V	0 to 5.4 V	0 to 5.7 V	Differences do not affect safety and effectiveness of intended use
Output Voltage (500 Ohms)	0 to 5.1 V	0 to 6.4 V	0 to 7.2 V	0 to 10.8 V	0 to 7.1 V	0 to 7.6 V	Differences do not affect safety and effectiveness of intended use
Output Voltage (800 Ohms)	0 to 8.2 V	0 to 7.5 V	0 to 8.0 V	0 to 11.6 V	0 to 8.4 V	0 to 9.6 V	Differences do not affect safety and effectiveness of intended use
Output Current (300 Ohms)	0 to 10.2 mA	0 to 13.5 mA	0 to 21 mA	0 to 23.3 mA	0 to 18.0 mA	0 to 19.0 mA	Differences do not affect safety and effectiveness of intended use

Comparator	Nalu Neurostimulation System (Subject Device)	Stimwave Freedom SCS system (K170141) (Primary Predicate)	Stimwave Freedom SCS system (K141399) (Reference Device)	Medtronic Mattrix 3271/3272 (K934065) (Reference Device)	Medtronic Xtrel 3425 (K883780) (Reference Device)	ANS Renew (K000852) (Reference Device)	Analysis of Technological Differences from Primary Predicate
Output Current (500 Ohms)	0 to 10.2 mA	0 to 12.8 mA	0 to 15 mA	0 to 21.6 mA	0 to 14.2 mA	0 to 15.2 mA	Differences do not affect safety and effectiveness of intended use
Output Current (800 Ohms)	0 to 10.2 mA	0 to 9.4 mA	0 to 10 mA	0 to 14.5 mA	0 to 10.5 mA	0 to 12.0 mA	Differences do not affect safety and effectiveness of intended use
Waveform	charge balanced (delayed) biphasic asymmetrical	Same	Same	Same	Same	Same	Same
Pulse Shape	Decaying Exponential	Decaying Exponential	Decaying Exponential	Decaying Exponential	Decaying Exponential	Decaying Exponential	Same
Maximum phase charge (300 Ohms)	10.2 µC/pulse	6.8 µC/pulse	10.5 µC/pulse	11.7 µC/pulse	18.0 µC/pulse	9.5 µC/pulse	Differences do not affect safety and effectiveness of intended use
Maximum phase charge (500 Ohms)	10.2 µC/pulse	6.4 µC/pulse	7.2 µC/pulse	10.8 µC/pulse	14.2 µC/pulse	7.6 µC/pulse	Differences do not affect safety and effectiveness of intended use
Maximum phase charge (800 Ohms)	10.2 µC/pulse	4.7 µC/pulse	5.0 µC/pulse	7.3 µC/pulse	10.5 µC/pulse	6.0 µC/pulse	Differences do not affect safety and effectiveness of intended use
Maximum charge density (300 Ohm)	83.3 $\mu C/cm^2$	53.1 $\mu C/cm^2$	82.5 $\mu C/cm^2$	97.2 $\mu C/cm^2$	150.0 $\mu C/cm^2$	73.1 $\mu C/cm^2$	Differences do not affect safety and effectiveness of intended use

Comparator	Nalu Neurostimulation System (Subject Device)	Stimwave Freedom SCS system (K170141) (Primary Predicate)	Stimwave Freedom SCS system (K141399) (Reference Device)	Medtronic Mattrix 3271/3272 (K934065) (Reference Device)	Medtronic Xtrel 3425 (K883780) (Reference Device)	ANS Renew (K000852) (Reference Device)	Analysis of Technological Differences from Primary Predicate
Maximum charge density (500 Ohm)	83.3 µC/cm^2	50.3 µC/cm^2	56.6 µC/cm^2	90.0 µC/cm^2	118.3 µC/cm^2	58.5 µC/cm^2	Differences do not affect safety and effectiveness of intended use
Maximum charge density (800 Ohm)	83.3 µC/cm^2	36.9 µC/cm^2	39.3 µC/cm^2	60.4 µC/cm^2	87.5 µC/cm^2	46.2 µC/cm^2	Differences do not affect safety and effectiveness of intended use
Maximum current density (300 Ohm)	83.3 mA/cm^2	106.1 mA/cm^2	165.1 mA/cm^2	194.4 mA/cm^2	150.0 mA/cm^2	146.2 mA/cm^2	Differences do not affect safety and effectiveness of intended use
Maximum current density (500 Ohm)	83.3 mA/cm^2	100.6 mA/cm^2	113.2 mA/cm^2	180.0 mA/cm^2	118.3 mA/cm^2	116.9 mA/cm^2	Differences do not affect safety and effectiveness of intended use
Maximum current density (800 Ohm)	83.3 mA/cm^2	78.6 mA/cm^2	78.6 mA/cm^2	120.8 mA/cm^2	87.5 mA/cm^2	92.3 mA/cm^2	Differences do not affect safety and effectiveness of intended use
Net Charge	0 uC	Same	Same	Same	Same	Same	Same
Average Phase Power (300 Ohms)	0.031 W/phase	0.053 W/phase	0.060 W/phase	0.132 W/phase	0.068 W/phase	0.070 W/phase	Differences do not affect safety and effectiveness of intended use
Average Phase Power (500 Ohms)	0.052 W/phase	0.073 W/phase	0.076 W/phase	0.166 W/phase	0.074 W/phase	0.090 W/phase	Differences do not affect safety and effectiveness of intended use
Average Phase Power (800 Ohms)	0.083 W/phase	0.062 W/phase	0.060 W/phase	0.131 W/phase	0.066 W/phase	0.100 W/phase	Differences do not affect safety and effectiveness of intended use

Comparator	Nalu Neurostimulation System (Subject Device)	Stimwave Freedom SCS system (K170141) (Primary Predicate)	Stimwave Freedom SCS system (K141399) (Reference Device)	Medtronic Mattrix 3271/3272 (K934065) (Reference Device)	Medtronic Xtrel 3425 (K883780) (Reference Device)	ANS Renew (K000852) (Reference Device)	Analysis of Technological Differences from Primary Predicate
Average Phase Power density (300 Ohms)	0.25 W/cm^2/phase	0.42 W/cm^2/phase	0.48 W/cm^2/phase	1.10 W/cm^2/phase	0.57 W/cm^2/phase	0.54 W/cm^2/phase	Differences do not affect safety and effectiveness of intended use
Average Phase Power density (500 Ohms)	0.51 W/cm^2/phase	0.58 W/cm^2/phase	0.59 W/cm^2/phase	1.38 W/cm^2/phase	0.62 W/cm^2/phase	0.69 W/cm^2/phase	Differences do not affect safety and effectiveness of intended use
Average Phase Power density (800 Ohms)	0.55 W/cm^2/phase	0.48 W/cm^2/phase	0.60 W/cm^2/phase	1.09 W/cm^2/phase	0.55 W/cm^2/phase	0.77 W/cm^2/phase	Differences do not affect safety and effectiveness of intended use
Pulse Delivery Mode	Continuous	Same	Same	Same	Same	Same	Same
Current Path options	Bipolar	Bipolar	Bipolar	Bipolar	Bipolar	Bipolar	Same
Program Cycle	Cycle through programs	Same	Details unavailable	Details unavailable	Details unavailable	Details unavailable	Same
Pulse Pattern	Fine tuning of pulse patterns (On/Off; If On, spans from 12 µs to 1000 µs)	Same	Details unavailable	Details unavailable	Details unavailable	Details unavailable	Same
Dosage Time	Allows for stimulation to be applied in periodic doses (On/Off; If On, spans from 1 ms to 25 ms)	Same (over span of several minutes, hours, and up to one day)	Details unavailable	Same (Cycle ON/OFF)	Same (Cycle ON/OFF)	Details unavailable	Differences do not affect safety and effectiveness of intended use

Comparator	Nalu Neurostimulation System (Subject Device)	Stimwave Freedom SCS system (K170141) (Primary Predicate)	Stimwave Freedom SCS system (K141399) (Reference Device)	Medtronic Mattrix 3271/3272 (K934065) (Reference Device)	Medtronic Xtrel 3425 (K883780) (Reference Device)	ANS Renew (K000852) (Reference Device)	Analysis of Technological Differences from Primary Predicate
Daily Therapy Time	Limits the number of hours in a day that stimulation may be used (Seconds to hours)	Same (hours)	Details unavailable	Details unavailable	Details unavailable	Details unavailable	Differences do not affect safety and effectiveness of intended use
Transmit Frequency	40.68 MHz	915 MHz	915 MHz	2 MHz	1.6 MHz	2 MHz	Differences do not affect safety and effectiveness of intended use

Table 5-4: Substantial Equivalence Table – External components

	Nalu Neurostimulation System (Subject Device)	**Stimwave Freedom SCS system (K170141) (Predicate)**	**Analysis of Technological Differences**
Externally worn devices			
Name	Therapy Disc and Trial Therapy Disc	Wearable Antenna Assembly (WAA)	NA
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
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
Antenna (Therapy Disc only)	Integrated antenna supporting 40.68 MHz power and data transfer.	Transmitting (Tx) Antenna Assembly, 915 MHz – An antenna and coaxial cable assembly that is attached to the WAA that is used to transmit microwave energy to the implanted Stimulator.	Differences do not affect safety and effectiveness of intended use
Wearing (Therapy Disc only)	Therapy Disc is positioned over Nalu IPG via two options: • Adhesive clip (hydrocolloid adhesive) • Elastic Belt	WAA worn in a Belt Antenna positioned over device using an elastic belt	Differences do not affect safety and effectiveness of intended use
Size/Weight	Disc: ~1. 5 cm thick, 7. 5 cm diameter Weight: ~0.08 kg	7.6 cm x 5 cm x 2 cm 0.5 kg	Differences do not affect safety and effectiveness of intended use
Externally contacting Materials	Biocompatible PC ABS housing. Occasional contact to fingers (e.g., button use). Textile material of belt may be worn directly on the skin. Hydrocolloid adhesive applied to skin.	Silicone and Aluminum (not to be worn on body). Occasional contact to fingers (e.g. button use). Textile material of belt may be worn directly on the skin. No adhesive option reported.	Differences do not affect safety and effectiveness of intended use
Battery Charging	Electrically isolated cradle charger	A battery and wire assembly for charging and for power delivery	Differences do not affect safety and effectiveness of intended use

Table 5-5: Substantial Equivalence Table – Clinician Programmer and Remote Control

	Nalu Neurostimulation System (Subject Device)	Stimwave Freedom SCS system (K170141) (Predicate)	Analysis of Technological Differences
Clinician Programmer			
Configuration	Software installed on a compatible Android tablet.	Software installed on an iPad	Differences do not affect safety and effectiveness of intended use
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	Same
Communication	Secure Bluetooth to Therapy Disc, Trial Therapy Disc, and Patient Remote Control.	Bluetooth	Differences do not affect safety and effectiveness of intended use
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.	NA	Differences do not affect safety and effectiveness of intended use

All of the physical and therapeutic attributes for the Nalu Neurostimulation system are within or equivalent to the parameters seen in the predicate and reference devices. There are no significant differences in these characteristics that would raise new questions of safety or effectiveness.

The Nalu Neurostimulation system includes a few features that are different from the predicate as listed below:

- Differences in surgical tools and components above are a reflection of the subtly different insertion techniques between Nalu and the various predicate devices.
- The Nalu Neurostimulation System comes with an adhesive wearable option that is not provided with the primary predicate but is provided with referenced predicate devices such as the Medtronic XTREL, K883780. The approach allows for reliable positioning of the external transmitter module over the Nalu IPG device.
- The Nalu Neurostimulation programming system's Therapy Discs provide the same physical controls as the predicate's WAA. An added feature to the Nalu Neurostimulation System is the option of a mobile app replicating these same controls through a smartphone interface. No clinical programming functions are available through the Patient Remote Control Application. The Patient Remote

Control Application cannot alter the state of the Therapy Disc or Trial Therapy Disc from the state configured by the Clinician Programmer.

5.8. **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 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.

5.8.1 Applicable Standards and Guidance Documents

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

Table 5-6: 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 60601-1:2005: A2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-11:2015	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 60601-1-2:2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

Standard Number	Title
IEC 60601-1-6:2010 +A1:2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability
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
IEC 62304:2015	Medical device software – Software life cycle processes
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: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices issued October 2, 2014	
FDA Guidance: Applying Human Factors and Usability Engineering to Medical Devices issued February 3, 2016	

5.8.2 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.

Biocompatibility testing was based upon the categorization of the different body-contacting components and duration of the Nalu Neurostimulation system. The categories are based upon the following classifications, per the FDA guidance:

- Implant Device, in Tissue, permanent contact duration (>30 days): Nalu IPG, Leads, Lead Anchor, Lead Extension
- Externally Communicating Device, in Tissue, limited contract duration (≤24 hours): Needles, Sheaths and other surgical tools
- Surface Device, intact skin contact, permanent duration (>30 days): Therapy Discs, Adhesive clip and belt

Testing included: cytotoxicity, sensitization, irritation or intracutaneous reactivity, systematic toxicity, implant studies, and chemical characterization. Biocompatibility was demonstrated.

5.8.3 Animal Testing

In the animal study, six Nalu Neurostimulation IPGs and Lead systems were implanted in a porcine model and evaluated over a period of 90 days. The purpose of the study included: evaluating the surgical usability of the Nalu components, demonstrating the RF communication and ensuing stimulation, observing implanted device stability, and observing tissue response in a live model over the implant time.

All devices performed as expected without incident and together provided pre-clinical validation of the safety and clinical use of the Nalu Neurostimulation System in a live model. There were no device- or procedure-related complications or premature deaths in this study. Data was collected at 30, 60 and 90 day intervals.

5.8.4 Summary of Nonclinical Performance Testing

Verification testing of the Nalu Neurostimulation System included electrical, mechanical and software 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.

5.9. **Clinical Performance Data**

Nalu Medical determined that bench and non-clinical testing are sufficient to demonstrate that the Nalu Neurostimulation system is as safe and effective as the predicate device. Note that the predicate device did not need clinical evidence to obtain a determination of substantial equivalence.

5.10. **Conclusions**

The bench and non-clinical data support the safety of the device and the hardware and the software verification and validation demonstrated that the Nalu Neurostimulation System performs as intended in the specified use conditions and the results of which do not raise new questions of safety and effectiveness.