



August 23, 2024

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

Re: K233801

Trade/Device Name: Nalu Neurostimulation System for Spinal Cord Stimulation;
Nalu Neurostimulation System for Peripheral Nerve Stimulation

Regulation Number: 21 CFR 882.5880

Regulation Name: Implanted Spinal Cord Stimulator For Pain Relief

Regulatory Class: Class II

Product Code: GZB, GZF

Dated: August 16, 2024

Received: August 16, 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
Physical Medicine Devices

OHT5: Office of Neuromodulation and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K233801

Device Name

Nalu Neurostimulation System for Spinal Cord Stimulation;
Nalu Neurostimulation System for Peripheral Nerve Stimulation

Indications for Use (Describe)

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.

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 Nalu Neurostimulation System for PNS 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: August 22, 2024

Device Names and Classification

510(k) Number: K233801

Primary Product Code	
Trade/Proprietary Name	<i>Nalu Neurostimulation System</i>
Common/Usual Name	<i>Stimulator, Spinal-Cord, Implanted (Pain Relief)</i>
Classification Regulation	<i>21 CFR 882.5880; Implanted spinal cord stimulator for pain relief</i>
Product Code	<i>GZB</i>
Class	<i>Class II</i>
Review Panel	<i>Neurology</i>
Secondary Product Code	
Trade/Proprietary Name	<i>Nalu Neurostimulation System</i>
Common/Usual Name	<i>Stimulator, Peripheral Nerve, Implanted (Pain Relief)</i>
Classification Regulation	<i>21 CFR 882.5870; Implanted peripheral nerve stimulator for pain relief</i>
Product Code	<i>GZF</i>
Class	<i>Class II</i>
Review Panel	<i>Neurology</i>

Predicate/Reference Devices

- Predicate Device: Nalu Neurostimulation System (for SCS & PNS) (K221376)
- Reference Device: Nalu Neurostimulation System for SCS (K202274)
- Reference Device: Nalu Neurostimulation System for Peripheral Nerve Stimulation (K183579)

Device Description

The Nalu Neurostimulation System (referred to as the “Nalu System”) incorporates a miniature implantable pulse generator (IPG), powered by an externally worn Therapy Disc device. The Nalu System therapy utilizes pulsed electrical current to create an energy field that acts on

peripheral nerves or central 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. This device is intended to be used in the spinal column as well as the peripheral nerves in arm, leg, pelvic and other areas, as is typical of other devices and treatments for the same intended use.

The Nalu System is intended for stimulation of the spinal cord or peripheral nerves for patients experiencing chronic, intractable pain. This system is indicated for pain management in adults who have severe intractable chronic pain, 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.

The Nalu System is comprised of the following components:

- Implantables (there are no proposed changes to these components as previously provided in K221376):
 - o Implantable pulse generator (IPG; available either as an integrated lead unit or with separately connected lead(s)) – provides electrical stimulation pulses that are transmitted through the leads, to the desired location, either on the spinal cord or peripheral nerve site(s).
 - o Leads – implantable and designed to deliver electrical pulses to the nerves via an array of four (4) or eight (8) cylindrical electrodes at the distal end.
 - o Surgical and Trial Tools – includes anchors, spoonbill needs, stylets, tearaway introducers, pocket tunneler, torque wrench, IPG insertion tool, straw tunneler; tools to support implantation of lead and IPG.
- Externals, Non-Sterile:
 - o Externally worn controllers (for use with the permanent implant) and accessories – includes the Therapy Disc, Adhesive Clip, Wearable Garment, Therapy Disc Charger; houses the battery and electronics for RF power and controls the IPG for therapy delivery via the remote programmer (subject of this submission).
 - o Externally worn stimulator (for use with the trial lead) and accessories – includes the Trial Therapy Disc; sends signals to the percutaneous leads during the trial period by way of the Electrode Interface Cable (EIC).
- Software (subject of this submission):
 - o Clinician Programmer, Patient Remote Control – used to configure the system parameters; also manages patient records, Therapy Discs and remote controls for patients with the Nalu System; runs on Android and iOS platforms and can be optionally used to control and manage Therapy Discs over a secure Bluetooth® Low Energy connection.

Technological characteristics of the device under review (non-sterile externals including the Therapy Disc and Therapy Disc Charger and the associated software updates) are identical to

that of the predicate device previously cleared under K221376, with the exception of minor electronics updates, updates to the user interfaces (which now include the use of gesture controls for BLE bond renegotiation), reduction of the size of the Therapy Disc (including updates to the wearable accessories to accommodate the new Therapy Disc size) and lastly, minor patient-contacting material updates. None of these technological differences in the device under review affect safety or efficacy of the Nalu System as they have been fully evaluated for equivalence through design Verification and Validation.

Indications for Use

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.

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 Nalu Neurostimulation System for PNS 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

This Traditional 510(k) premarket notification is for the proposed device, the Nalu Neurostimulation System (inclusive of both the SCS and PNS indications), which is a modification of the cleared Nalu Neurostimulation System (K221376). Nalu is proposing design modifications to the externally worn controller (i.e., Therapy Disc and Base Station), as well as software application updates (i.e., Clinician Programmer and Remote Control). The modifications outlined in this 510(k) do not raise different questions of safety or effectiveness as demonstrated by the completed testing provided within this submission. Based on the similarities between the cleared and modified devices, the proposed Nalu System is substantially equivalent to the cleared Nalu Neurostimulation System (K221376). Provided in Table 1 is a comparison of the cleared and modified devices which includes a rationale for substantial equivalence.

Of note, the implanted components, surgical tools, and therapy settings remain unchanged. The modifications made to the Nalu System described herein only impact the external control device referred to as the Therapy Disc and the Therapy Disc Base Station (charger) as well as the Clinician Programmer and Remote-Control Application Software.

Please also note that the second-generation Therapy Disc, Base Station Charger and accessories as well as the updated PC and RC software applications are to be used in both FDA cleared indications for use, Spinal Cord Stimulation (SCS) and Peripheral Nerve Stimulation (PNS).

Table 1: Substantial Equivalence Comparison

	Nalu Neurostimulation System for SCS & PNS K233801 (Proposed Device)	Nalu Neurostimulation System for SCS & PNS K221376 (Predicate Device)	Comparison
Product Code and Classification	GZB, Class II GZF, Class II	GZB, Class II GZF, Class II	Same as predicate.
Regulation	SCS: 21 CFR §882.5880 PNS: 21 CFR §882.5870	SCS: 21 CFR §882.5880 PNS: 21 CFR §882.5870	Same as predicate.
Classification Name	SCS: Implanted spinal cord stimulator for pain relief PNS: Implanted peripheral nerve stimulator for pain relief	SCS: Implanted spinal cord stimulator for pain relief PNS: Implanted peripheral nerve stimulator for pain relief	Same as predicate.
Intended Use	SCS: Stimulation of the spinal cord for treatment of chronic, intractable pain PNS: Stimulation of peripheral nerves for chronic, intractable pain	SCS: Stimulation of the spinal cord for treatment of chronic, intractable pain PNS: Stimulation of peripheral nerves for chronic, intractable pain	Same as predicate.
Indications for Use	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. 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 Nalu Neurostimulation System for PNS 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.	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. 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.	Same as predicate.
Prescription Use	Yes	Yes	Same as predicate.
Implant Site	SCS: Lead: Epidural space IPG: Subcutaneous, mid back PNS:	SCS: Lead: Epidural space IPG: Subcutaneous, mid back PNS:	Same as predicate.

	Peripheral nerves, excluding craniofacial region.	Peripheral nerves, excluding craniofacial region.	
Environmental Use	Hospital Use, Home	Hospital Use, 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	SCS: MR Conditional Labeling for Head and Extremities. Full Body MR Conditional Labeling for Full Body. PNS: MR Conditional Labeling for Head and Extremities.	Not publicly available	SCS: Same as reference device K202274. PNS: Same as reference device K183579.
External Device Names	Therapy Disc (second generation), Base Station Charger and Trial Therapy Disc	Therapy Disc and Trial Therapy Disc	Therapy Disc and Therapy Disc Charger (Base Station) have updated design. Trial Therapy Disc remains unchanged.
Electronics	Updated folded printed circuit board (PCB) design that generates RF power with embedded waveform parameter settings that can be changed 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	Functional output of TD2 electronics remains unchanged. PCB changes were evaluated through usability and EMC testing to confirm there are no different questions of safety or effectiveness.
User Interface	Integrated indicators allow the user to monitor device status. Therapy Disc can be controlled through flip gesture. The Remote Control allows the user to stop/start stimulation, increase or decrease therapy levels, and select from configured therapy profiles.	Integrated controls and indicators that allow the user to turn the device on/off, increase or decrease therapy levels, select from configured therapy profiles and monitor device status.	Gesture controls on Therapy Disc replace buttons. Changes were evaluated through usability testing to confirm there are no different questions of safety or effectiveness.
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.
Wearable Garments and Adhesive Clips (Therapy Disc Only)	Therapy Disc is positioned over Nalu IPG via two options: • Adhesive clip (hydrocolloid adhesive) • Elastic Belt/Cuff Wearable accessories design has been updated to accommodate smaller footprint TD2 device	Therapy Disc is positioned over Nalu IPG via two options: • Adhesive clip (hydrocolloid adhesive) • Elastic Belt/Cuff	New adhesive clip using same materials. Updated Elastic Belt/Cuff. Changes were evaluated through usability testing to confirm there are no different questions of safety or effectiveness.
Size/Weight	Disc: ~1.3 cm thick, ~6.2 cm diameter Weight: ~0.06 kg	Disc: ~1.5 cm thick, 7.5 cm diameter Weight: ~0.08 kg	Similar. The size/weight

			modifications do not raise different questions of safety or effectiveness. Dimensional verification confirms that the device meets its specifications.
Externally Contacting Materials	Biocompatible PC ABS housing. Occasional contact to fingers (e.g., taking disc in and out of adhesive clip or wearable garment. 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.	Similar as predicate. Biocompatible PC ABS housing materials for the bottom housing have not changed. The patient contacting materials of the TD2 top housing are similar to the top housing of the predicate device, the differences in the top housing materials do not raise different questions of safety or effectiveness. The biological evaluation of these materials poses a very low biocompatibility risk because they have a long history of safe use in legally marketed medical devices that contact intact skin.
Battery Charging	Electrically isolated cradle charger compatible with Therapy Disc devices.	Electrically isolated cradle charger compatible with Therapy Disc devices.	Same as predicate.
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, Patient Remote Control and Clinician Programmer. Clinician Programmer and Base Station Charger (BSC) also upload/download encrypted data using a secure connection to a Nalu cloud service via a Wi-Fi access point.	Secure Bluetooth to Therapy Disc, Trial Therapy Disc, Patient Remote Control and Clinician Programmer. Device usage information is stored offline on the Therapy Disc and can be transferred to the Clinician Programmer via BLE connection	Same methods of communication. Changes were evaluated through usability and Software testing to confirm there are no different questions of safety or effectiveness.
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 devices	Software app installed on compatible mobile device (Android/iOS) providing wireless selection among preconfigured options and status readout for paired Therapy Disc devices.	Same as predicate.

Table 2: Predicate and Subject Device Comparison with the Nalu Neurostimulation therapy delivery (SCS and PNS)

Comparator	Nalu Neurostimulation System (Subject Device, K233801)	Nalu Neurostimulation System (Predicate Device, K221376)	Analysis of Technological Differences from Predicate
Pulse Frequency	2 Hz to 1500 Hz	2 Hz to 1500 Hz	Same as predicate
Pulse Width	12 to 2000 μ s	12 to 2000 μ s	Same as predicate
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
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)	18.0 $\mu\text{C}/\text{pulse}$	18.0 $\mu\text{C}/\text{pulse}$	Same as predicate
Maximum phase charge (500 Ohms)	18.0 $\mu\text{C}/\text{pulse}$	18.0 $\mu\text{C}/\text{pulse}$	Same as predicate
Maximum phase charge (800 Ohms)	18.0 $\mu\text{C}/\text{pulse}$	18.0 $\mu\text{C}/\text{pulse}$	Same as predicate
Maximum charge density (300 Ohm)	146.94 $\mu\text{C}/\text{cm}^2$	146.94 $\mu\text{C}/\text{cm}^2$	Same as predicate
Maximum charge density (500 Ohm)	146.94 $\mu\text{C}/\text{cm}^2$	146.94 $\mu\text{C}/\text{cm}^2$	Same as predicate
Maximum charge density (800 Ohm)	146.94 $\mu\text{C}/\text{cm}^2$	146.94 $\mu\text{C}/\text{cm}^2$	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 μC	0 μC	Same as predicate
Average Phase Power (300 Ohms)	0.031 W/phase	0.031 W/phase	Same as predicate
Average Phase	0.052 W/phase	0.052 W/phase	Same as predicate

Power (500 Ohms)			
Average Phase Power (800 Ohms)	0.083 W/phase	0.083 W/phase	Same as predicate.
Average Phase Power density (300 Ohms)	0.25 W/cm ² /phase	0.25 W/cm ² /phase	Same as predicate.
Average Phase Power density (500 Ohms)	0.51 W/cm ² /phase	0.51 W/cm ² /phase	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	Fine tuning of pulse patterns (On/Off; If On, spans from 12 μ s to 1000 μ s)	Fine tuning of pulse patterns (On/Off; If On, spans from 12 μ s to 1000 μ s)	Same as predicate.
Dosage Time	Allows for stimulation to be applied in periodic doses (On/Off; If On, spans from 1 ms to 1000 ms, If Off, spans from 1 ms to 2000 ms)	Allows for stimulation to be applied in periodic doses (On/Off; If On, spans from 1 ms to 1000 ms, If Off, spans from 1 ms to 2000 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 Comparison

The Nalu Neurostimulation System has the same intended use and Indications for Use as the predicate device (K221376). Of note, the implanted components, surgical tools, and therapy settings remain unchanged. The modifications made to the Nalu Neurostimulation System described herein only impact the external control device referred to as the Therapy Disc and the Therapy Disc Base Station (charger) as well as the Clinician Programmer and Remote

Control Application software. The differences between the Nalu Neurostimulation System and the predicate device (K221376) do not raise any different questions of safety or effectiveness as confirmed through non-clinical testing.

Non-Clinical and/or Clinical Test Summary & Conclusions

The testing performed for the Nalu Neurostimulation System was developed in accordance with Nalu Medical, Inc. (Nalu)'s Quality System, including Design Control and Risk Management, per ISO 14971: 2019-12. Design Controls apply to all medical devices manufactured by Nalu in accordance with ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes, 21 CFR Part 820.

The testing performed consisted of the following:

- Verification and Validation Testing for second-generation Therapy Disc (TD2) System, including the following:
 - EMC testing in accordance with 60601-1 Edition 3.2 2020-08, 60601-1-2 Edition 4.0 2014-02, 60601-1-2 Edition 4.1 2020-09, 60601-1-6 Edition 3.2 2020-07, 60601-1-11 Edition 2.1 2020-07
 - Packaging Validation in accordance with ISTA 3A 2018
 - Biocompatibility testing in accordance with ISO 10993-1:2018
 - Software testing in accordance with IEC 62304 Edition 1.1 2015-06, Content of Premarket Submissions for Device Software Functions, *Guidance for Industry and Food and Drug Administration Staff published on June 14, 2023*, and General Principles of Software Validation, *Guidance for Industry and FDA Staff published on January 11, 2002*.
 - Formative & Summative Usability Testing for TD2 System, in accordance with 62366-1 Edition 1.1 2020-06

No clinical testing was performed.

Testing demonstrated that the Nalu Neurostimulation System has been verified to perform in accordance with its product specifications, in support of its intended use.