June 10, 2022

Nalu Medical, Inc.
Chelsea Gutierrez
VP Regulatory and Quality
2320 Faraday Avenue, Suite 100
Carlsbad, California 92008

Re: K221376
Trade/Device Name: Nalu Neurostimulation System
Regulation Number: 21 CFR 882.5880
Regulation Name: Implanted Spinal Cord Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: GZB, GZF
Dated: May 12, 2022
Received: May 12, 2022

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 (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221376

Device Name
Nalu Neurostimulation System

Indications for Use *(Describe)*

Spinal Cord Stimulation (SCS)
This system is indicated as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain.
The trial devices are solely used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) device.

Peripheral Nerve Stimulation (PNS)
This system is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. The system is not intended to treat pain in the craniofacial region.

The trial devices are solely used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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1. Submission Sponsor

Nalu Medical, Incorporated
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Carlsbad, CA 92008
Phone: (714) 401-0608
Fax: (760) 448-2377
Contact: Chelsea Gutierrez
Vice President of Regulatory Affairs and Quality Assurance

2. Date Prepared: June 10, 2022

3. Device Names and Classification

Primary Product Code	
Proprietary Name	Nalu Neurostimulation System
Common Names	Stimulator, Spinal-Cord, Implanted (Pain Relief)
Class	II
Classification Regulation	21 CFR 882.5880; Implanted spinal cord stimulator for pain relief
Product Code	GZB
Review Panel	Division of Neurology

Secondary Product Code	
Proprietary Name	Nalu Neurostimulation System
Common Names	Stimulator, Peripheral Nerve, Implanted (Pain Relief)
Class	II
Classification Regulation	21 CFR 882.5870; Implanted peripheral nerve stimulator for pain relief
Product Code	GZF
Review Panel	Division of Neurology

4. Predicate Device(s)

Nalu Neurostimulation System, K203547

For software differences between the Nalu Neuromodulation System and the predicate(s) (K203547), substantial equivalence to the predicate device is demonstrated.

5. Device Description

The Nalu Neurostimulation System has been cleared by the FDA for spinal cord stimulation (SCS; K203547) and peripheral nerve stimulation (PNS; K203547) to provide therapeutic relief for chronic, intractable pain of the trunk and/or limbs including unilateral, bilateral nerve pain. The Nalu Neurostimulation therapy utilizes pulsed

electrical current to create an energy field that acts on nerves in the spinal cord or peripheral nerve to inhibit the transmission of pain signals to the brain. The Nalu System is implanted only following a successful trial period using the Nalu Neurostimulation trial system.

The Nalu Neurostimulation System consists of five (5) components. The implantable pulse generator (IPG) provides electrical stimulation pulses that are transmitted through the leads, to the desired location, either on the spinal cord or peripheral nerve site. The leads are implantable and designed to deliver electrical pulses to the nerves via an array of four (4) or eight (8) cylindrical electrodes at the distal end. The Trial Therapy Disc or the Therapy Disc houses the battery and electronics for RF power and controls the IPG for therapy delivery via the remote programmer. Implantation of the Nalu IPG and lead components for Spinal Cord Stimulation (SCS) or Peripheral Nerve Stimulation (PNS) is performed via standard surgical tools and techniques, as described in (K203547).

6. Indications for Use

Spinal Cord Stimulation (SCS)

This system is indicated as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain.

The trial devices are solely used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long-term) device.

Peripheral Nerve Stimulator (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.

7. Comparison with the Predicate Device

Table 1: Nalu Neuromodulation System for Spinal Cord Stimulation (SCS)

Device	Nalu Neuromodulation System (Subject Device, K221376)	Nalu Neuromodulation System (Predicate Device, K203547)	Analysis of Technological Differences
510(k)	K221376	K203547	N/A
Product Code and Class	GZB and GZF, Class II	GZB and GZF, Class II	Same
Regulation Number	21 CFR 882.5880 (GZB) 21 CFR 882.5870 (GZF)	21 CFR 882.5880 (GZB) 21 CFR 882.5870 (GZF)	Same
Classification Name	Implanted spinal cord stimulator for pain relief. (GZB) Implanted peripheral nerve stimulator for pain relief. (GZF)	Implanted spinal cord stimulator for pain relief. (GZB) Implanted peripheral nerve stimulator for pain relief. (GZF)	Same
Trade Name	Nalu Neuromodulation System	Nalu Neurostimulation System	Same
Manufacturer	Nalu Medical, Inc.	Nalu Medical, Inc.	Same
Intended Use	The Nalu Neuromodulation system is intended for the stimulation of the spinal cord for treatment of chronic, intractable pain (GZB). Stimulation of peripheral nerves for chronic, intractable pain (GZF).	The Nalu Neuromodulation system is intended for the stimulation of the spinal cord for treatment of chronic, intractable pain (GZB). Stimulation of peripheral nerves for chronic, intractable pain (GZF).	Same
Indications for Use	For Spinal Cord Stimulation- This system is indicated as the	For Spinal Cord Stimulation- This system is indicated as the	Same

Device	Nalu Neuromodulation System (Subject Device, K221376)	Nalu Neuromodulation System (Predicate Device, K203547)	Analysis of Technological Differences
	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. For Peripheral Nerve Stimulation- 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	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. For Peripheral Nerve Stimulation- 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	

Device	Nalu Neuromodulation System (Subject Device, K221376)	Nalu Neuromodulation System (Predicate Device, K203547)	Analysis of Technological Differences
	stimulation (no longer than 30 day) to determine efficacy before recommendation for a permanent (long term) device.	stimulation (no longer than 30 day) to determine efficacy before recommendation for a permanent (long term) device.	
Clinical application	Treatment of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain.	Treatment of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain.	Same
Prescription Use	Yes	Yes	Same
Environmental Use	Hospital, Home	Hospital, Home	Same
Intended Clinician	Orthopedic, Neurosurgeon, Anesthesiologist	Orthopedic, Neurosurgeon, Anesthesiologist	Same
Intended User	Physician, Layperson	Physician, Layperson	Same
Implant site, leads	Epidural space (SCS) or peripheral nerve areas (PNS)	Epidural space (SCS) or peripheral nerve areas (PNS)	Same
Principle of Operation	Stimulation of the spinal cord to provide therapeutic relief for chronic, intractable pain of the trunk and/or limbs including unilateral or bilateral pain.	Stimulation of the spinal cord to provide therapeutic relief for chronic, intractable pain of the trunk and/or limbs including unilateral or bilateral pain.	Same
Mode of Action	RF wireless transmission of energy to deliver stimulation at stimulator electrodes.	RF wireless transmission of energy to deliver stimulation at stimulator electrodes.	Same
Software Level of Concern	Moderate	Moderate	Same
Clinician Programmer	Software to communicate to	Not publicly available	The differences do not impact the safety and

Device	Nalu Neuromodulation System (Subject Device, K221376)	Nalu Neuromodulation System (Predicate Device, K203547)	Analysis of Technological Differences
	Trial Therapy or Therapy Disc Manual control of current for selected electrodes and optional model based allocation.		effectiveness of the device. The safety parameters (charge per phase, charge density and current density) remain unchanged. The updated software allows the clinician to optionally use a mode to set the current values on up to 4 electrodes based on a model. The safety limits continue to be applied as before. The new method is an option that may allow programming to go faster when causing the current steering stimulation mode. As with all programming in neurostimulation the patient remains in the feedback loop and determines the effectiveness of the therapy.
Patient Remote Control	Software to pair with Trial Therapy or Therapy Disc SW update to reflect changes on the Clinician Programmer and	Not publicly available	-

Device	Nalu Neuromodulation System (Subject Device, K221376)	Nalu Neuromodulation System (Predicate Device, K203547)	Analysis of Technological Differences
	Remote Control		
Externally worn devices	Trial Therapy Disc and Therapy Disc Firmware update to reflect changes on the Clinician Programmer and Remote Control	Not publicly available	-
Labelling Clinician Programmer User Guide/Remote Control User Guide	Labeling updated to support Clinical Programmer Current Steering options.	Not publicly available	The differences to labeling do not impact the safety and effectiveness of the device.

Table 2: Nalu Neuromodulation System for Peripheral Nerve Stimulation

Device	Nalu Neuromodulation System (Subject Device, K221376)	Nalu Neuromodulation System (Predicate Device, K203547)	Analysis of Technological Differences
510(k)	K221376	K203547	N/A
Product Code and Class	GZB and GZF, Class II	GZB and GZF, Class II	Same
Regulation Number	21 CFR 882.5880 (GZB) 21 CFR 882.5870 (GZF)	21 CFR 882.5880 (GZB) 21 CFR 882.5870 (GZF)	Same
Classification Name	Implanted spinal cord stimulator for pain relief. (GZB)	Implanted spinal cord stimulator for pain relief. (GZB)	Same

Device	Nalu Neuromodulation System (Subject Device, K221376)	Nalu Neuromodulation System (Predicate Device, K203547)	Analysis of Technological Differences
	Implanted peripheral nerve stimulator for pain relief. (GZF)	Implanted peripheral nerve stimulator for pain relief. (GZF)	
Trade Name	Nalu Neuromodulation System	Nalu Neurostimulation System	Same
Manufacturer	Nalu Medical, Inc.	Nalu Medical, Inc.	Same
Intended Use	The Nalu Neuromodulation system is intended for the stimulation of the peripheral nerve for treatment of chronic, intractable pain.	The Nalu Neuromodulation system is intended for the stimulation of the peripheral nerve for treatment of chronic, intractable pain.	Same
Indications for Use	This system is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. The system is not intended to treat pain in the craniofacial region. The trial devices are solely used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long-term) device.	This system is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. The system is not intended to treat pain in the craniofacial region. The trial devices are solely used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long-term) device.	Same

Device	Nalu Neuromodulation System (Subject Device, K221376)	Nalu Neuromodulation System (Predicate Device, K203547)	Analysis of Technological Differences
Clinical application	Treatment of chronic peripheral nerve pain.	Treatment of chronic peripheral nerve pain.	Same
Prescription Use	Yes	Yes	Same
Environmental Use	Hospital, Home	Hospital, Home	Same
Intended Clinician	Orthopedic, Neurosurgeon, Anesthesiologist	Orthopedic, Neurosurgeon, Anesthesiologist	Same
Implant site, leads	Epidural space (SCS) or peripheral nerve areas (PNS)	Epidural space (SCS) or peripheral nerve areas (PNS)	Same
Intended User	Physician, Layperson	Physician, Layperson	Same
Principle of Operation	Stimulation of the peripheral nerve to provide therapeutic relief for chronic, pain.	Stimulation of the peripheral nerve to provide therapeutic relief for chronic, pain.	Same
Mode of Action	RF wireless transmission of energy to deliver stimulation at stimulator electrodes.	RF wireless transmission of energy to deliver stimulation at stimulator electrodes.	Same
Software Level of Concern	Moderate	Moderate	Same
Clinician Programmer	Software to communicate to Trial Therapy or Therapy Disc Manual control of current for selected electrodes and optional model based allocation.	Not publicly available .	The differences do not impact the safety and effectiveness of the device. The safety parameters (charge per phase, charge density and current density) remain unchanged. The updated software allows the clinician to optionally use a mode to set the

Device	Nalu Neuromodulation System (Subject Device, K221376)	Nalu Neuromodulation System (Predicate Device, K203547)	Analysis of Technological Differences
			current values on up to 4 electrodes based on a model. The safety limits continue to be applied as before. The new method is an option that may allow programming to go faster when causing the current steering stimulation mode. As with all programming in neurostimulation the patient remains in the feedback loop and determines the effectiveness of the therapy.
Patient Remote Control	Software to pair with Trial Therapy or Therapy Disc SW update to reflect changes on the Clinician Programmer and Remote Control	Not publicly available	-
Externally worn devices	Trial Therapy Disc and Therapy Disc Firmware update to reflect changes on the Clinician Programmer and Remote Control	Not publicly available	-
Labelling	Labeling updated to support Clinical Programmer	Not publicly available	The differences to labeling do not impact the safety

Device	Nalu Neuromodulation System (Subject Device, K221376)	Nalu Neuromodulation System (Predicate Device, K203547)	Analysis of Technological Differences
Clinician Programmer User Guide/Remote Control User Guide	Current Steering options.		and effectiveness of the device.

Table 3 Predicate and Subject Device comparison with the Nalu Neurostimulation therapy delivery (SCS and PNS)

Comparator	Nalu Neurostimulation System (Subject Device, K221376)	Nalu Neurostimulation System (Predicate Device, K203547)	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 µs	12 to 2000 µs	Same as predicate
Current/Volta ge 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

Comparator	Nalu Neurostimulation System (Subject Device, K221376)	Nalu Neurostimulation System (Predicate Device, K203547)	Analysis of Technological Differences from 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 µC/pulse	18.0 µC/pulse	Same as predicate
Maximum phase charge (500 Ohms)	18.0 µC/pulse	18.0 µC/pulse	Same as predicate
Maximum phase charge (800 Ohms)	18.0 µC/pulse	18.0 µC/pulse	Same as predicate
Maximum charge density (300 Ohm)	146.94 µC/cm^2	146.94 µC/cm^2	Same as predicate

Comparator	Nalu Neurostimulation System (Subject Device, K221376)	Nalu Neurostimulation System (Predicate Device, K201618)	Analysis of Technological Differences from Predicate
Maximum charge density (500 Ohm)	146.94 µC/cm^2	146.94 µC/cm^2	Same as predicate
Maximum charge density (800 Ohm)	146.94 µC/cm^2	146.94 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 µC	0 µC	Same as predicate
Average Phase Power (300 Ohms)	0.031 W/phase	0.031 W/phase	Same as predicate

Comparator	Nalu Neurostimulation System (Subject Device, K221376)	Nalu Neurostimulation System (Predicate Device, K201618)	Analysis of Technological Differences from 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 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 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	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

Comparator	Nalu Neurostimulation System (Subject Device, K221376)	Nalu Neurostimulation System (Predicate Device, K203547)	Analysis of Technological Differences from 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

8. Technological Characteristics

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

9. Summary of Nonclinical Performance Testing

Nalu Medical performed a range of testing to gather data supporting the safety and performance of the Nalu Neurostimulation System prior to use. Nalu follows the Design Controls section of 21 CFR 820.30, ISO 14971, and ISO 13485:2016. These standards ensure that all designs are appropriately evaluated and tested. The system is designed and tested to ensure that it meets all applicable standards and guidance documents. The subject device of this 510(k) has similar technological and performance criteria to the predicate device(s). The proposed changes on the Clinician Programmer specifications to increase therapy options are within the limits that have been previously cleared in predicate and reference devices. Validation and performance testing demonstrate that the device meets the performance criteria as reflected in the functional specifications. All of the required testing and results from the predicate devices (K203547) remain applicable to the subject device of this 510(k) except for the updated software and firmware validation testing to support the proposed changes that are included in this submission.

Table 4: Standards and Guidance Documents

Standard Number	Title
EN ISO 14971:2012	Medical devices -- Application of risk management to medical devices

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
BS EN 62311-2008	Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields
ANSI IEEE C63.27	American National Standard for Evaluation of Wireless Coexistence
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	
Refuse to Accept Policy for 510(k)s dated September 13, 2019	
“eCopy Program for Medical Device Submissions” dated April 27, 2020	
“Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Premarket Submissions for Medical Devices” (September 14, 2018)	
“Deciding When to Submit a 510(k) for a Software Change to an Existing Device dated Oct 25th 2017	
The Special 510(k) Program: Guidance for Industry and Food and Drug Administration Staff	
Providing Regulatory Submissions for Medical Devices in Electronic Format – Submissions under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry and Food and Drug Administration Staff	

10. 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.

11. Conclusions

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. Risk analysis of the proposed changes did not raise any different questions of safety and effectiveness.