July 11, 2019

Nalu Medical, Inc.
Sunny Gill
Senior Quality Assurance and Regulatory Affairs Specialist
2320 Faraday Avenue, Suite 100
Carlsbad, California 92008

Re: K190960
Trade/Device Name: Nalu Lead Blank (50cm)
Regulation Number: 21 CFR 882.5880
Regulation Name: Implanted Spinal Cord Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: GZB
Dated: April 11, 2019
Received: April 12, 2019

Dear Sunny Gill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

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

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

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

Sincerely,

Pamela Scott
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190960

Device Name
Nalu Lead Blank

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.

The Nalu Lead Blank is an optional accessory intended to be used as a surgical aide to insert the Nalu Neurostimulation System Leads.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5.1. Submission Sponsor

Nalu Medical, Incorporated
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Contact: Sunny Gill, Senior Quality Assurance and Regulatory Affairs Specialist

5.2. Date Prepared

July 11, 2019

5.3. Device Identification

Trade/Proprietary Name: Nalu Lead Blank
Common/Usual Name: Lead Blank
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)

Nalu Neurostimulation System (K183047) by Nalu Medical, Inc.

5.5. Device Description

The Nalu Lead Blank is an optional accessory to the Nalu Neurostimulation System (also referred to as the "Nalu System"), which 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. The Nalu Lead Blank is an optional non-implantable surgical tool used during implant of the Nalu Neurostimulation System leads. The Nalu Lead Blank may be used to create a path for the lead in the epidural space.

5.6. Indications for Use Statement

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 than 30 days) to determine efficacy before recommendation for a permanent (long term) device. The Nalu Lead Blank is an optional accessory intended to be used as a surgical aide to insert the Nalu Neurostimulation System Leads.

The Indications for Use statement for the Nalu Lead Blank is identical to the predicate device. Both the subject and predicate devices have the same intended use, which is for the stimulation of the spinal cord for treatment of chronic, intractable pain.

5.7. Substantial Equivalence Discussion

The primary predicate for this submission is the Nalu Neurostimulation System that was most recently cleared in K183047. The Nalu System is intended for adult patients and contains a lead that has the same intended use as the lead blank. The Nalu Lead Blank is an optional non-implantable surgical tool used during implant of the Nalu Neurostimulation System leads. The Nalu Lead Blank is used to create a path for the lead in the epidural space. With this submission, there is no change to the Nalu neurostimulator, leads, external components, or therapy.

For areas where slight differences occur between the Nalu Lead Blank and the primary predicate (K183047), substantial equivalence to a reference device in this same product code is demonstrated. The Stimwave Freedom 8 SCS System cleared in K170141 is used as the reference device since the design of the lead blank and its sole purpose is more aligned with the guide wire used as part of the Stimwave Freedom 8 SCS System. This reference device was used as part of the predicate history to the primary predicate in this submission. The 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 8 SCS System	K170141	K162161
Nalu Neurostimulator System (Primary Predicate)	K183047	K170141

The following table compares the Nalu Lead Blank to the predicate device and the reference 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. Summary information on the Nalu device, predicate device and reference device are provided in **Table 5-2** below:

Table 5-2: Substantial Equivalence Table – Primary predicate and Reference Device Summary

	Nalu Lead Blank (Subject Device)	**Nalu Neurostimulation System (Primary Predicate)**	**Stimwave Freedom 8 SCS system (K170141) (Reference Device)**	**Analysis of Technological Differences from Primary Predicate**
510(k)	K190960	K183047	K170141	NA
Product Code and class	GZB, Class II	Same	Same	Same
Regulation number	21 CFR 882.5880	Same	Same	Same
Classification name	Implanted spinal cord stimulator for pain relief.	Same	Same	Same
Intended Use	Stimulation of spinal cord for chronic, intractable pain	Same	Same	Same
Indications for Use	This system is indicated as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain. The trial devices are solely used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) device. The Nalu Lead Blank is an optional accessory intended to be used as a surgical aide to insert the Nalu Neurostimulation System Leads.	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.	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 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
Prescription Use?	Yes	Same	Same	Same
Anatomical site	Epidural space	Same	Same	Same

	Nalu Lead Blank (Subject Device)	Nalu Neurostimulation System (Primary Predicate)	Stimwave Freedom 8 SCS system (K170141) (Reference Device)	Analysis of Technological Differences from Primary Predicate
Environmental Use	Hospital, Home	Same	Same	Same
Intended Clinician	Orthopedic, Neurosurgeon, Anesthesiologist	Same	Same	Same
Intended User	Physician, Layperson	Same	Same	Same

Physical characteristics of the implantable components of the Nalu Lead Blank, the lead within the Nalu Neurostimulation System (primary predicate) and the guide wire within the Stimwave reference device are compared in **Table 5-3** below.

Table 5-3: Predicate and Reference Device comparison with the Nalu Lead Blank

	Nalu Lead Blank (Subject Device)	Lead within Nalu Neurostimulation System (K183047) (Primary Predicate)	Guide wire within the Stimwave Freedom 8 SCS system (K170141) (Reference Device)	Analysis of Technological Differences from Primary Predicate
Device Function	Create a pathway in the epidural space for the lead to follow	The stimulating portion of the neurostimulator that is inserted into the epidural space and creates a pathway through its insertion.	Create a pathway in the epidural space for the lead to follow	Optional device meant to enhance the surgical experience compared to the primary predicate. Same as reference device.
Construction	Flexible coiled wire	Flexible multilumen extrusion consisting of 8 (1x19) lead wires and 8 contacts	Flexible coiled wire	Optional device meant to enhance the surgical experience compared to the primary predicate. Same as reference device
Material	Stainless steel	Multilumen extrusion made of 55D Pellethane; lead wires made of 35NLT-DFT-28%AG (ETFE COATED); and contacts made of (90/10) PT/IR	Stainless steel	Optional device meant to enhance the surgical experience compared to the primary predicate. Same as reference device
Duration of Use	Surgical procedure	Duration of long-term implant (>30 days)	Surgical procedure	Optional device meant to enhance the surgical

	Nalu Lead Blank (Subject Device)	Lead within Nalu Neurostimulation System (K183047) (Primary Predicate)	Guide wire within the Stimwave Freedom 8 SCS system (K170141) (Reference Device)	Analysis of Technological Differences from Primary Predicate
	Implant tool, limited (≤24 hrs)		Implant tool, limited (≤24 hrs)	experience compared to the primary predicate. Same as reference device
Length	50 cm	40 cm, 60 cm	Unpublished	Differences do not affect safety and effectiveness of intended use
Diameter	1.30 mm	1.30 mm	Unpublished	Differences do not affect safety and effectiveness of intended use
Packaging	Tyvek and Mylar pouch	Tyvek and Mylar pouch	Unpublished	Same
Sterilization Type	Ethylene Oxide	Same sterilization site and cycle	Ethylene Oxide	Same

All of the physical and therapeutic attributes for the Nalu Lead Blank 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 information above supports the conclusion that the Nalu Lead Blank has the same intended use as the predicate and reference devices.

5.8. Nonclinical Performance Testing

Nalu Medical performed a range of testing to gather data supporting the safety and performance of the Nalu Lead Blank for its intended use. Nalu followed the Design Controls section of 21 CFR 820.30, ISO 14971:2007, and ISO 13485:2016. These procedures ensured that all designs were appropriately planned, defined, evaluated, transferred to production, and ongoing changes are reviewed for impact on safety and effectiveness and appropriately evaluated and tested. The Nalu Lead Blank 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 was also performed on the device. Validation and performance testing demonstrate that the device acceptably meets user needs as reflected in the product requirements.

5.8.1 Applicable Standards and Guidance Documents

The testing for the Nalu Lead Blank includes the following test standards and guidance:

Table 5-4: Standards and Guidance Documents

Standard Number	Title
ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 11070:2014	Sterile single-use intravascular introducers, dilators and guidewires
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
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
EN ISO 14971:2012 ISO 14971:2007	Medical devices -- Application of risk management to medical devices
IEC 62366-1:2015	Medical Devices – Part 1: Application of usability engineering to medical devices
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 body-contacting component and duration of the Nalu Lead Blank. The category was based upon the following classification, per the FDA guidance:

- implant tool for tissue/bone contact for a limited duration (≤ 24 hours)

Testing included: cytotoxicity, sensitization, intracutaneous reactivity, and systematic toxicity. Biocompatibility was demonstrated.

5.8.3 Animal Testing

Animal Testing was not a necessary part of the verification and validation testing for the Nalu Lead Blank. Instead, usability of the Nalu Lead Blank was evaluated in a Surgical Validation cadaver lab.

5.8.4 Summary of Nonclinical Performance Testing

Verification testing of the Nalu Lead Blank included mechanical 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 Lead Blank is as safe and effective as the predicate and reference device.

5.10. Conclusions

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