May 13, 2026

Helius Medical, Inc
Lawrence Picciano
VP Regulatory and Quality
642 Newtown Yardley Road
Suite 100
Newtown, Pennsylvania 18940

Re: K253061
Trade/Device Name: Portable Neuromodulation Stimulator (PoNS)
Regulation Number: 21 CFR 882.5889
Regulation Name: Electrical tongue stimulator to treat motor deficits
Regulatory Class: Class II
Product Code: QCF
Dated: July 28, 2025
Received: September 22, 2025

Dear Lawrence Picciano:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

CHUN XU -S

For 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253061

Device Name
Portable Neuromodulation Stimulator (PoNS)

Indications for Use *(Describe)*
The PoNS device is indicated for use as a treatment of dynamic gait deficit due to chronic symptoms from stroke and is to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over by prescription only.

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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510(k)SUMMARY

SUBMISSION NUMBER: K253061 DEVICE SUBMITTER
Helius Medical, Inc
642 Newtown Yardley Road Suite 100
Newtown, PA 18940
Phone: 732-648-7332

CONTACT: Lawrence Picciano
DATE PREPARED: May 13, 2026

DEVICE
NAME OF DEVICE: Portable Neuromodulation Stimulator (PoNS™)
REGULATION NUMBER: 21 CFR 882.5889
REGULATION NAME: Electrical tongue nerve stimulator to treat motor deficits
CLASSIFICATION: Class II
PRODUCT CODE: QCF

PREDICATE DEVICE: Portable Neuromodulation Stimulator (PoNS™) (DEN200050)

DEVICE DESCRIPTION

Both the current PoNS (Portable Neuromodulation Stimulator) device and the predicate PoNS device (authorized under DEN200050) are electrical tongue nerve stimulators to treat motor deficits (Regulation 21 CFR 882.5889, Product Code QCF). The subject PoNS device (K253061) is identical to the predicate device (authorized under DEN200050). No changes have been made to the device or system design or functionality. Therefore, a single technical description applies to both the subject and predicate devices.

The term PoNS “Device” is used to describe the components that deliver the mild electrotactile stimulation to the surface of a patient’s tongue, i.e., the Controller and Mouthpiece. The PoNS system comprises the Controller, Mouthpiece, Charger, and the PoNS software. Also supplied are a cable for connection to a computer running the PoNS Software, a Mouthpiece Retainer Case and a Product Carry Case.

Figure 1: PoNS Device, Controller and Mouthpiece

The PoNS System is a tongue stimulator that delivers a mild electrotactile stimulation to the dorsal surface the patient's tongue via the Mouthpiece comprised of 143 gold-plated electrodes. Patients experience a comfortable sensation of vibration, tingle, or pressure on the surface of their tongue during stimulation.

The PoNS hardware is designed and constructed using materials that are widely used in medical device applications. The material properties are demonstrated suitable for use in the PoNS application.

The figure below shows the complete packaged PoNS system provided to patients: Mouthpiece Retainer Case, Carry Case, Charger, USB cable, and Instructions for use.

Figure 2: Packaged PoNS System

The PoNS Controller is the core of the system, comprising the primary user interface and electronics that deliver the stimulation waveform to the Mouthpiece. The Controller is worn by the patient around their neck during use and is used to power the system on and off, start and stop stimulation, and adjust the intensity of the stimulation. The Controller user interface comprises the control buttons, visual display, audio feedback and vibration feedback. The Controller is powered by a rechargeable 3.7V nominal LiPo battery. A coin-cell battery is used as the real-time clock back-up battery.

The Mouthpiece houses the 143-electrode array through which the electrotactile stimulation is applied to the dorsal surface of the patient's tongue. The Mouthpiece is placed in the patient's mouth. Electronics and software within the Mouthpiece control the timing of the stimulation. The Controller sends commands to the Mouthpiece and receives status messages from the Mouthpiece via the Mouthpiece cable.

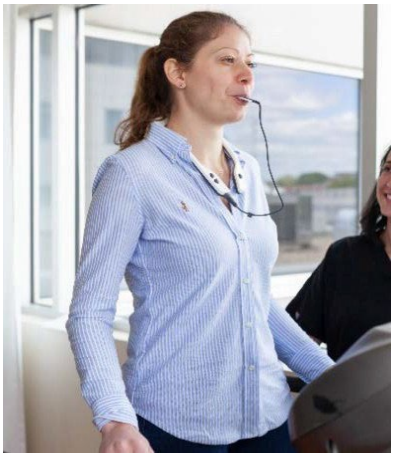

Figure 3: Patient Using PoNS

INDICATIONS FOR USE

The PoNS device is indicated for use as a treatment of dynamic gait deficit due to chronic symptoms from stroke and is to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over by prescription only.

TECHNOLOGICAL CHARACTERISTICS COMPARISON

The device characteristics of the subject PoNS device (K253061) are identical to those of the predicate PoNS device (DEN200050). No changes have been made to the device design, materials, or energy source since DEN200050 was granted. The table below compares the technological characteristics of the subject and predicate devices.

General Device Characteristics	**Predicate Device (DEN200050)**	**Subject Device (K253061)**	**Comparison**
Trade Name	Portable Neuromodulation Stimulator (PoNS™)	Portable Neuromodulation Stimulator (PoNS™)	
IFU	The PoNS device is indicated for use as a short term treatment of gait deficit due to mild to moderate symptoms from multiple sclerosis and is to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over by prescription only.	The PoNS device is indicated for use as a treatment of dynamic gait deficit due to chronic symptoms from stroke and is to be used as an adjunct to a supervised therapeutic exercise program in patients 22 years of age and over by prescription only.	Different. The subject PoNS device is indicated as a treatment of dynamic gait deficit due to chronic symptoms from stroke. The predicate PoNS device is indicated as a short term treatment of gait deficit due to mild to

			moderate symptoms from multiple sclerosis. However, these differences do not alter the intended use of the device, nor do they raise different questions of safety and effectiveness relative to the predicate device.
Waveform (e.g., pulsed monophasic, biphasic)	Pulsed biphasic (unbalanced)	Pulsed biphasic (unbalanced)	Same
Shape (e.g., rectangular, spike, rectified sinusoidal)	Rectangular	Rectangular	Same
Maximum Output Voltage (volts) (+/- 5%)	17.5V @ 500 Ω 20V @ 5 kΩ	17.5V @ 500 Ω 20V @ 5 kΩ	Same
Maximum Output Current (specify units) (+/- 5%)	3.5 mA @ 500Ω (Channel: 26 mA) 440 uA @ 5 kΩ (Channel: 3.85 mA)	3.5 mA @ 500Ω (Channel: 26 mA) 440 uA @ 5 kΩ (Channel: 3.85 mA)	Same
Duration of primary (depolarizing) phase (µsec)	60 µsec	60 µsec	Same
Pulse Duration (µsec)	312.5 µsec	312.5 µsec	Same
Frequency (Hz) [or Rate (pps)]	Triplets at 200 Hz intervals, repeating every 50 Hz Channel pulses stimulating different tongue locations at 3.2 kHz; Groups of 16 channel pulses delivered in triplets at 200 Hz; repeats every 50 Hz	Triplets at 200 Hz intervals, repeating every 50 Hz Channel pulses stimulating different tongue locations at 3.2 kHz; Groups of 16 channel pulses delivered in triplets at 200 Hz; repeats every 50 Hz	Same
Net Charge (microcoulombs (µC) per pulse)	-0.002 @ 500 Ω (Channel - 0.016) -0.0041 @ 5 kΩ (Channel - 0.036)	-0.002 @ 500 Ω (Channel - 0.016) -0.0041 @ 5 kΩ (Channel - 0.036)	Same
Maximum Phase Charge, (µC)	0.21 @ 500 Ω (Channel 1.56)	0.21 @ 500 Ω (Channel 1.56)	Same
Maximum Current Density (mA/cm^2, rms)	18.79 @ 500 Ω 2.36 @ 5 kΩ	18.79 @ 500 Ω 2.36 @ 5 kΩ	Same
Maximum Average Current (average absolute value), (mA)	0.082 @ 500 Ω 0.009 @ 5 k Ω	0.082 @ 500 Ω 0.009 @ 5 k Ω	Same
Maximum Average Power Density, (W/cm^2)	0.025 @ 500 Ω 0.0041 @ 5 k Ω	0.025 @ 500 Ω 0.0041 @ 5 k Ω	Same

SUMMARY OF NONCLINICAL AND BENCH STUDIES

Shelf life, electromagnetic compatibility, electrical safety, software, and human factors/usability testing were conducted to support the subject PoNS device. As the subject device is identical to the predicate device, biocompatibility testing was leveraged from the predicate device (DEN200050).

SHELF LIFE

The PoNS is not sold sterile, nor is it intended to be sterilized by the user or clinician. The mouthpiece is intended for use by a single user throughout their supervised therapeutic exercise program.

Real time age testing and material stability analysis were conducted to support a shelf life of 4 years for the PoNS Mouthpiece (storage period prior to first use). The Controller has a 3-year use life, determined by a combination of accelerated age testing, analysis of Controller material stability and physical testing. The use life of the mouthpiece (14 weeks) is unchanged from the predicate device.

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

The PoNS was tested to demonstrate compliance with the following applicable electrical safety and electromagnetic compatibility ("EMC") standards:

- IEC 60601-1:2005/A2:2020 – Safety assessment against the essential requirements and review of the Risk Management against ISO 14971:2019
- IEC 60601-1-2:2020 – EMC emissions and immunity
- IEC 60601-1-11:2015/A1:2020 – Environmental, pressure and IP22 testing relevant for the Home Healthcare Environment
- IEC 60601-2-10:2012/A2:2023 – Safety assessment against the essential requirements for nerve and muscle stimulators.

SOFTWARE

The PoNS System software documentation provided fulfills the requirements for a Basic Documentation level in support of the PoNS and is consistent with applicable requirements defined in FDA's *Guidance for the Content of Premarket Submissions for Device Software Functions* (June 2023). Documentation is provided to support compliance with FDA Guidance *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions* (June 2025). Cyber Threat analysis concludes the PoNS Software System poses no risk to patient or Health Care Professional safety.

HUMAN FACTORS/USABILITY

A human factors engineering process was implemented throughout the course of developing the PoNS system pursuant to FDA's 2016 guidance, Applying Human Factors and Usability Engineering to Medical Devices, ISO 14971 Medical Devices—Application of risk management to medical devices and recognized standards BS EN 62366-1 Edition 1.1 2020-06, Application of usability engineering to medical devices and IEC 60601-1-6, General requirements for basic safety and essential performance - Collateral standard: Usability. Human factors validation testing found the PoNS system to be safe for its intended use by the intended user population in both clinical and home environments.

SUMMARY OF CLINICAL INFORMATION

The effectiveness and safety of the PoNS for the proposed stroke indication were evaluated in 3 clinical trials across 10 sites, enrolling 152 chronic stroke survivors with gait deficit due to stroke. The trials included:

- One pivotal sponsor-initiated double-blind, randomized, placebo-controlled study (SIT), which enrolled 64 participants across 5 sites;
- One pivotal sponsor-initiated single arm (open-label) study (OLS), which enrolled 38 subjects across 5 sites; and
- One pilot investigator-initiated double-blind, randomized, placebo-controlled study (IIT), which enrolled 50 participants at 2 sites.

All studies were designed to assess the effectiveness and safety of PoNS device used in conjunction with routine physical rehabilitation therapy (study treatment) over a 12-week treatment period. Participants were required to perform 60 minutes of study treatment per day, at least 3-4 times per week for 12 weeks (minimum treatment adherence requirement), 4 weeks in clinic under the supervision of a PoNS-trained physical therapist, and then at home independently for the remaining 8 weeks of treatment. Participants were then followed for 12 weeks after completion of treatment to assess durability of treatment effect.

Effectiveness

This study evaluated the improvement in dynamic gait function, measured by the Functional Gait Assessment (FGA).

In the primary analysis of the combined SIT+OLS studies, active PoNS treatment plus physical rehabilitation led to a clinically meaningful adjusted mean change in FGA of 5.18 points (95% CI: 4.31 to 6.06) from baseline to Week 12. Subjects treated with sham PoNS plus physical rehabilitation experienced a non-clinically meaningful change of 3.31 points (95% CI 1.96 to 4.76). Comparing the proportion of subjects who achieved response in the PoNS +Physical Therapy (PT) group as compared to sham + PT, 45% more subjects achieved response in the PoNS group using a 6-point threshold (56.1% vs 11.1%) and at least 30% more subjects achieved response in the PoNS group at a ≥4-point improvement threshold (63.1% vs 33.3%). A similar result was observed employing a threshold of a 5-point improvement (58.5% vs 33.3%).

Overall, clinical data demonstrated that a greater proportion of subjects in the active PoNS group achieved clinically meaningful individual-level improvements in gait function compared to sham, from baseline to 12 weeks, as measured by FGA. Durability of the FGA benefit was demonstrated at 12 weeks, with 89.7% (95% CI 81.8% to 97.5%) of subjects retaining at least 70% of their Week 12 FGA score at Week 24.

Safety

The primary safety endpoint was determined by establishing the incidence of serious treatment-related adverse events in each of the three studies. The study success criterion was based on demonstrating superiority for either endpoint. Type 1 error was controlled using the Hochberg method.

The PoNS therapy was found to be safe and well-tolerated. Combining all data sources, including

the above 3 studies, the incidence rate of treatment-related SAEs was 0. The incidence of non-serious treatment related adverse events by study and treatment, across the SRP studies, ranged between 0.0% and 14.8%. There was no evidence that the incidence of non-serious treatment-related AEs differed between those on active and sham therapy.

CONCLUSION

The subject PoNS device has the same intended use and similar indications for use as the predicate PoNS device (DEN200050). The minor differences in indications for use do not alter the intended use of the device and do not raise different questions of safety and effectiveness. The technological characteristics and principles of operation remain unchanged. Clinical evidence demonstrates the effectiveness of PoNS therapy in improving gait deficit in chronic stroke survivors when used as an adjunct to a supervised therapeutic exercise program. The PoNS device was safe and well-tolerated by patients in both the clinic and home settings. Therefore, the subject PoNS device is substantially equivalent to the predicate device.