November 22, 2024

Neuvotion Inc.
Chad Bouton
President and CEO
165 Club Rd
Stamford, Connecticut 06905

Re: K240632
Trade/Device Name: Neuvotion NeuStim (NN-01)
Regulation Number: 21 CFR 882.5810
Regulation Name: External Functional Neuromuscular Stimulator
Regulatory Class: Class II
Product Code: GZI, IPF
Dated: October 31, 2024
Received: November 1, 2024

Dear Chad Bouton:

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.

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,

Amber T. Ballard -S

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)*
K240632

Device Name
Neuvotion NeuStim NN-01

Indications for Use *(Describe)*
The NeuStim NN-01 is an electrical stimulation device indicated for the following uses:

Functional Electrical Stimulation (FES):

Improvement of hand function and active range of motion in patients with hemiplegia due to stroke or upper limb paralysis due to C5 spinal cord injury.

NeuroMuscular Electrical Stimulation (NMES):

- Maintaining or increasing hand range of motion;
- Prevention or retardation of disuse atrophy;
- Increasing local blood circulation;
- Relaxation of muscle spasms; and
- Muscle re-education.

The NeuStim NN-01 is intended for use on the right arm/right hand 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

Contact Details 21 CFR 807.92(a)(1):

Neuvotion Inc.
165 Club Rd.
Stamford, CT 06905

Mr. Chad Bouton
Email: boutonce@neuvotion-inc.com
Tel: 614.561.1140

Date Prepared: November 22, 2024

Device Name 21 CFR 807.92(a)(2):

Device Trade Name: Neuvotion NeuStim NN-01
Common Name: External functional neuromuscular stimulator
Classification Name: Stimulator, Neuromuscular, External Functional
Regulation Number: 882.5810
Product Codes: GZI, IPF

Legally Marketed Predicate Devices 21 CFR 807.92(a)(3):

K123636, Bioness NESS H200 Wireless Hand Rehabilitation System
Product Codes GZI, IPF

Device Description Summary 21 CFR 807.92(a)(4):

The NeuStim Model NN-01 (herein Device) consists of a voltage-controlled generating source that connects to disposable electrodes that are worn by the patient on the anterior and posterior forearm and around the thumb, these are named the Flexor, Extensor and Thumb Disposable Electrodes respectively. The disposable electrodes consist of multiple contacts that can stimulate the muscles in different areas of the forearm and thumb with 10kHz voltage pulses generated by the NeuStim voltage-controlled stimulator.

The Device is classified as a Functional Electrical Stimulation (FES) and NeuroMuscular Electrical Stimulation (NMES) device. The Device uses galvanic electrical energy to evoke muscle contractions.

The Device has 181 addressable electrode contacts enabling fine spatial resolution of stimulation to the patient. The Device allows manual electrode scanning to facilitate rapid mapping of effective stimulation points, which can be stored for use in future sessions. This rapid scanning capability is enabled through the use of solid-state relay technology embedded in the flexible patches that mate directly with the disposable electrodes. The motion of the user's (i.e. licensed healthcare professional) finger on the screen of the NeuStim™ Tablet electronically steers the stimulation point through the use of a solid-state relay matrix in each patch and thumb dongle, while lighting LED indicators on the back of the patch/dongle under control. This allows immediate, dynamic visual indication of the stimulation location which facilitates rapid mapping (i.e. user can quickly find and return to useful stimulation points). When the user observes desired muscle activations and associated wrist, hand, or finger movements, the related stimulation locations can be stored as a pattern. Up to three of these stored patterns can then be combined into a compound move where the stimulator will continuously time multiplex between them to allow for

compound motion. Finally, up to three compound moves or patterns can be combined into a sequence where each of the selected compound moves or patterns are applied for a user configurable number of seconds.

The Device uses a stimulation pulse repetition rate of 50 Hz. The stimulation pulse is comprised of a multiphasic (5 cycle) waveform with a total duration of 0.5 ms. The stimulation output (peak) voltage is less than 65V (500 Ohm load) and less than 120V (10,000 Ohm load). The stimulation output power will not exceed 0.25 W/cm^2 (averaged over one second) into a 500 Ohm Load.

Indications for Use 21 CFR 807.92(a)(5):

The NeuStim NN-01 is an electrical stimulation device indicated for the following uses:

Functional Electrical Stimulator (FES):

Improvement of hand function and active range of motion in patients with hemiplegia due to stroke or upper limb paralysis due to C5 spinal cord injury.

NeuroMuscular Electrical Stimulation (NMES):

- Maintenance and/or increase of hand range of motion;
- Prevention or retardation of disuse atrophy;
- Increasing local blood circulation;
- Relaxation of muscle spasms; and
- Muscle re-education

The NeuStim NN-01 is intended for use on the right arm/right hand only.

Device/ Characteristic	**NESS H200 Wireless (K123636) Predicate Device**	**NeuStim Model NN-01 (K240632) Subject Device**	**Comparison Results**
Indications for Use 21CFR807.92(a)(5)			
1. Indications for Use	Functional Electrical Stimulation (FES): - Improvement of hand function and active range of motion in patients with hemiplegia due to stroke or upper limb paralysis due to C5 spinal cord injury. NeuroMuscular Electrical Stimulation (NMES): - Maintenance and/or increase of hand range of motion - Prevention and/or retardation of disuse atrophy - Increase in local blood circulation - Reduction of muscle spasm	Functional Electrical Stimulation (FES): Improvement of hand function and active range of motion in patients with hemiplegia due to stroke or upper limb paralysis due to C5 spinal cord injury. NeuroMuscular Electrical Stimulation (NMES): - Maintenance and/or increase of hand range of motion - Prevention or retardation of disuse atrophy - Increasing local blood circulation - Relaxation of muscle spasms - Muscle re-education	Equivalent Subject Device is identical with a subset of Predicate Device, i.e. right arm/right hand

Device/ Characteristic	NESS H200 Wireless (K123636) Predicate Device	NeuStim Model NN-01 (K240632) Subject Device	Comparison Results
	- Re-education of muscles	The NeuStim NN-01 is intended for use on the right arm/right hand only.	
2. Intended Use Environment	Used both for therapy session in a professional healthcare facility and for patient to take home	Used for therapy session only in a professional healthcare facility by a licensed practitioner	Equivalent Subject Device is identical with a subset of Predicate Device
3. Prescription or OTC?	Prescription	Prescription	Identical
4. Target Population	Patients with hemiplegia due to stroke or upper limb paralysis due to C5 spinal cord injury	Patients with hemiplegia due to stroke or upper limb paralysis due to C5 spinal cord injury	Identical
5. Anatomical Site	Not publicly available	The NeuStim NN-01 stimulates the following muscles: – Extensor Digitorum, Extensor Pollicis Brevis and Longus – Thenar Muscle Group – Flexor Digitorum Superficialis, Flexor Pollicis Longus	Identical

Technological Comparison 21 CFR 807.92(a)(6):

Device/ Characteristic	NESS H200 Wireless (K123636) Predicate Device	NeuStim Model NN-01 (K240632) Subject Device	Comparison Results
Basic Unit Characteristics Summary (Guidance Document for Powered Muscle Stimulators, Attachment II, Section 2)			
1. 510(k) Number	K123636	K240632	N/A
2. Device Name, Model	NESS H200 Wireless	NeuStim NN-01	N/A
3. Manufacturer	Bioness	Neuvotion Inc.	N/A
4. Power Source(s)	Rechargeable battery	Internally powered (secondary Lithium Ion battery)	Identical
	Not publicly available	Wireless (inductive) charging	Equivalent
– Method of Line Current Isolation	Not publicly available	n/a	n/a
– Patient Leakage Current Normal Condition	Not publicly available	Meets 60601-1 Clause 8.7 limits	Identical
– Patient Leakage Current Single Fault Condition	Not publicly available	Meets 60601-1 Clause 8.7 limits	Identical
5. Number of Output Modes	Not publicly available	One (1)	Identical
6. Number of Output Channels	Not publicly available	Two (2)	Different
– Synchronous or Alternating?	Not publicly available	Synchronous	Indeterminate
– Method of Channel Isolation	Not publicly available	Transformer	Indeterminate
7. Regulated Current or Regulated Voltage?	Not publicly available	Regulated Voltage	Different Subject Device safe by design since current limiting hardware circuitry employed
8. Software/ Firmware/ Microprocessor Control?	Not publicly available	Yes	Identical
9. Automatic Overload Trip?	Not publicly available	Yes	Identical
10. Automatic No-Load Trip?	Not publicly available	No	Different

Device/ Characteristic	NESS H200 Wireless (K123636) Predicate Device	NeuStim Model NN-01 (K240632) Subject Device	Comparison Results
			Subject Device safe by design since voltage mode is used and current-limiting hardware circuitry employed
11. Automatic Shut Off?	Not publicly available	No	Different Subject Device safe since used under clinical staff direct supervision
12. Patient Override Control?	Not publicly available	Yes	Identical
13. Indicator Display – On/Off Status?	Not publicly available	Yes	Identical
– Low Battery?	Not publicly available	Yes	Identical
– Voltage/Current Level	Not publicly available	Yes	Identical
14. Timer Range (minutes)	Not publicly available	n/a	Different Subject Device safe since used under clinical staff direct supervision
15. Compliance with Voluntary Standards	Yes IEC 60601-1, IEC 60601-1-2	Yes IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, ES60601-1, ISO 10993-5, ISO 10993-10, IEC 62133-2, IEEE ANSI C63.27-2017. AAMI TIR69:2017	Equivalent Subject device conforms to additional safety and performance standards
16. Compliance with 21 CFR 898	Not publicly available	Yes	Identical
17. Weight	Not publicly available	55g	N/A
18. Dimensions (in.) [W x H x D]	Not publicly available	Length: 2.34in Width: 1.87in Depth: .91in	N/A
19. Housing Materials and Construction	Not publicly available	Polymer Housing, Silicone Rubber, Velcro Straps	Identical

Device/ Characteristic	NESS H200 Wireless (K123636) Predicate Device	NeuStim Model NN-01 (K240632) Subject Device	Comparison Results
			Subject Device safe per ISO 10993 testing and per FDA Biocompatibility Guidance Attachment G, Section B
Output Specifications (Guidance Document for Powered Muscle Stimulators, Attachment II, Section 3)			
Waveform (e.g., pulsed monophasic, biphasic)	Not publicly available	Multiphasic	Different Subject Device uses voltage mode, but safe by design since charge-balanced and maximum power density level is below limit of 0.25W/cm^2 to prevent excess tissue heating
Shape (e.g., rectangular, spike, rectified sinusoidal)	Not publicly available	Sinusoidal	Different Subject Device uses voltage mode, but safe by design since charge-balanced and maximum power density level is below limit of 0.25W/cm^2 to prevent excess tissue heating
Maximum Output Voltage (volts) (+/- ___%) at 500 Ohms, 2k Ohms and 10k Ohms	Not publicly available	55.9 @ 500Ω 87.4V @ 2000Ω 105.5V @ 10000Ω	Different Subject Device uses voltage mode, but safe by design. The maximum voltage and current values are

Device/ Characteristic	NESS H200 Wireless (K123636) Predicate Device	NeuStim Model NN-01 (K240632) Subject Device	Comparison Results
			instantaneous maximum values for a high-frequency (very short phase duration) stimulation waveform. Since the phase duration is significantly lower (0.05ms vs. the predicate durations of 0.1, 0.2, 0.3 ms). Therefore the resulting maximum phase charge is substantially equivalent to the Predicate Device.
Maximum Output Current (specify units) (+/- ___%) at 500 ohms, 2k Ohms and 10k Ohms	Not publicly available	111.9 mA @ 500Ω 43.7 mA @ 2000Ω 10.6 mA @ 10000Ω	Different Subject Device uses voltage mode, but safe by design. The maximum voltage and current values are instantaneous maximum values for a high-frequency (very short phase duration) stimulation waveform. Since the phase duration is significantly lower (0.05ms vs. the predicate durations of 0.1, 0.2, 0.3 ms). Therefore the resulting maximum phase charge is substantially

Device/ Characteristic	NESS H200 Wireless (K123636) Predicate Device	NeuStim Model NN-01 (K240632) Subject Device	Comparison Results
			equivalent to the Predicate Device.
Pulse width (specify units)	Not publicly available	0.5 milliseconds	Equivalent
Frequency	Not publicly available	50 Hz	Equivalent
Symmetrical phases? (yes/no)	Not publicly available	Yes	Identical
Phase Duration (include units), (state range, if applicable), (both phases, if asymmetrical)	Not publicly available	0.05 milliseconds	Equivalent The shorter phase duration of the Subject Device results in decreased apparent tissue impedance thereby allowing increased current delivery for a given voltage level resulting in effective muscle contractions.
Net Charge (uC per pulse) (If zero, state method of achieving zero net charge)	Not publicly available	0, Balanced Waveform	Identical
Maximum Phase Charge (mC)	Not publicly available	0.00408 mC	Equivalent
Maximum Current Density (RMS) (mA/cm^2)	Not publicly available	1.78 mA/cm^2 (500 Ohm Load)	Different Subject Device safe by design as maximum current density level is below limit of 2 mA/cm^2 per IEC 60601-2-10 to prevent excess tissue heating
Maximum Power Density, (W/cm^2), (using smallest electrode conductive surface area)	Not publicly available	0.0563 W/cm^2 (500 Ohm Load)	Different Subject Device safe by design as maximum power density level is

Device/ Characteristic	NESS H200 Wireless (K123636) Predicate Device	NeuStim Model NN-01 (K240632) Subject Device	Comparison Results
			below limit of 0.25W/cm^2 to prevent excess tissue heating
Burst Mode (i.e. Pulse trains): – Pulses per burst – Bursts per second – Burst duration (seconds) – Duty Cycle: Line (b) x Line (c)	Not publicly available	N/A	N/A
ON Time (seconds)	Not publicly available	Variable	Identical
OFF Time (seconds)	Not publicly available	Variable	Identical
Additional Features (if applicable)	– Intelli-Connect Earpiece Trigger Device	n/a	N/A
Description of Accessories (Guidance Document for Powered Muscle Stimulators, Attachment II, Section 4) Section 4 applies to only to the Subject Device.			
Description of Software/Firmware/Microprocessor Control (Guidance Document for Powered Muscle Stimulators, Attachment II, Section 5)			
1. Determination of the level of concern	Not publicly available	Basic Documentation Level	Subject device complies with current regulations and FDA Guidance
2. Description of all device functions controlled by the software	Not publicly available	Start / Stop Stimulation Stimulation Amplitude Stimulation Location Stimulation Pattern LED Indicators Pairing with Control Device Monitor and Display Battery Levels Entering Sleep Mode	Equivalent

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b):

Purpose	Testing	Results
Verify compliance with ANSI/AAMI ES60601-1 and IEC 60601-1 requirements for basic safety and essential performance	Battery powered device, Type BF Applied Parts	Passed
Verify compliance with IEC 60601-1-2 requirements for basic safety and essential performance Electromagnetic Disturbances	Battery powered device; radiated emissions, radiated field immunity, proximity filed immunity, magnetic field immunity, electrostatic discharge immunity	Passed
Verify compliance with IEC 60601-2-10 requirements for the safety and essential performance of nerve and muscle stimulators	Battery powered muscle stimulator, Type BF Applied Parts, normal and single-fault, energy and power limits	Passed
Verify compliance with ISO 10993-1 Biologic Evaluation of Medical Devices	Part 5: Tests for in vitro cytotoxicity; Part 10: Tests for irritation and skin sensitization	Passed
Verify compliance with IEC 62133-2 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems	Battery individual cells and packs certified via third party testing	Passed
Verify software meets requirements	Software Verification and Validation	Passed
Verify user needs are met	System Design Validation	Passed
Verify device meets requirements	Design Verification	Passed
Verify device meets IEEE/ANSI C63.27 Coexistence Testing	Tier 2	Passed
Verify device meets labeled Shelf-Life.	Shelf-Life Validation Study	Passed
Verify device meets Adhesive Performance Criteria	Adhesive Performance Validation Study	Passed
Verify device meets Current Distribution (Dispersion) and Electrode Impedance Criteria	Power and Current Density Validation Study	Passed

Summary of Clinical Testing:

Not Applicable

Conclusion: The NeuStim NN-01 Device has the same intended use, does not raise any different questions of safety and effectiveness, and the provided performance data demonstrate substantial equivalence to the cleared Bioness Ness H200 System (K123636).