October 11, 2019

NeuX Technologies, Inc.
% Christopher Devine, PhD
President
Devine Guidance International, Inc.
4730 South Fort Apache Road, Suite 300
Las Vegas, Nevada 89147

Re: K191181
Trade/Device Name: NXPRO Neuromuscular Electrical Stimulation Device
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: July 12, 2019
Received: July 17, 2019

Dear Dr. Christopher Devine:

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,

For Vivek Pinto, Ph.D.
Director (Acting)
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)*
K191181

Device Name
NXPRO Neuromuscular Electrical Stimulation Device

Indications for Use *(Describe)*
The NeuX NXPRO Neuromuscular Electrical Stimulation Device is intended for the stimulation of healthy muscles in order to improve or facilitate muscle performance.

The NeuX NXPRO is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. The NeuX NXPRO is not designed for use on injured or ailing muscles and its use on such muscles is contraindicated.

The NeuX NXPRO's electrical impulses allow triggering action potential on motor neurons of motor nerves (excitations). These excitations of motor neurons are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, & total session duration), different types of muscle work can be imposed on the stimulated muscles.

The various types of muscle work that the NeuX NXPRPO can impose on the stimulated muscles are able to improve or facilitate muscle performance. The NeuX NXPRO is considered a technique of muscle training.

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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Section Five (5) - 510(k) Summary

510(k) SUMMARY

[As Required by 21 CFR 807.92(c)]

Submitter's Name & Address: NeuX Technologies, Inc.
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Tampa, FL 33612

Contact Person: Christopher J. Devine, Ph.D.
Telephone (702) 939-5507
Mobile (702) 917-0585
Chris.devine@devineguidanceinternational.com

Date Summary Prepared: 11 October 2019

Device Name: Trade/Proprietary Name – NXPRO Neuromuscular Electrical Stimulation Device

Common/Usual Name – Powered Muscle Stimulator

Classification Name – Powered Muscle Stimulator (890.5850), Product Code NGX

Predicate Device – ARP Manufacturing – ARP Sport Device (K093999)

Reference Device – N/A

Device Description

The NeuX NXPRO Neuromuscular Electrical Stimulation Device generates electrical impulses the result in a triggering action potential on motor neurons of motor nerves (excitations). These excitations of motor neurons are transmitted to the muscle fibers through the system electrodes where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses: (a) pulse frequency; (b) duration of muscle contraction; (c) duration of rest; and (d) total session duration; different types of muscle work can be imposed on the stimulated muscles. The various types of muscle work that the NXPRO can impose on the stimulated muscles are able to improve or facilitate muscle performance.

Note: the application of the NXPRO is considered a technique of muscle training.

Intended Use

The NeuX NXPRO Neuromuscular Electrical Stimulation Device is intended for the stimulation of healthy muscles in order to improve or facilitate muscle performance.

The NeuX NXPRO is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. The NeuX NXPRO is not designed for use on injured or ailing muscles and its use on such muscles is contraindicated.

The NeuX NXPRO's electrical impulses allow triggering action potential on motor neurons of motor nerves (excitations). These excitations of motor neurons are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, & total session duration), different types of muscle work can be imposed on the stimulated muscles.

The various types of muscle work that the NeuX NXPRPO can impose on the stimulated muscles are able to improve or facilitate muscle performance. The NeuX NXPRO is considered a technique of muscle training.

Technological Characteristics/Principles of Operation

Technological Characteristics

Storage and Transportation Conditions

The NXPRO may be used either indoors or outdoors. However, if used outdoors, the NXPRO should not be exposed to rain, snow, condensing fog or condensing humidity, and should not be subjected to long-term exposure to direct sunlight.

Storage Environmental Conditions:

- -10°C to +60°C
- +5°C to +35°C at a relative humidity up to 90%, non-condensing
- +35°C to 70°C at a water vapor pressure up to 50 hPa

Operating Environmental Conditions:

- +5°C to +40°C
- Relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapor partial pressure greater than 50 hPa
- Atmospheric pressure range of 700 hPa to 1060 hPa

Disposal:

- Electronics must be disposed of in compliance with relevant national regulatory requirements.

  Note: the NeuX NXPRO device and components used in the manufacture of the NXPRO are RoHS compliant.

Standards:

- The NXPRO complies with current medical standards.
- The NXPRO also complies with the IEC 60601-1 standard on general safety requirements for electro-medical devices, IEC 60601-1-11 general requirements for basic safety and essential performance, ty requirements for electro-medical devices, the IEC 60601-1-2 standard on electromagnetic compatibility, and the IEC 60601-2-10 standard on particular safety requirements for nerve and muscle stimulators.

Output Waveform:

- A continuous, medium amplitude, sensory waveform, periodically broken by high amplitude, rectangular stimulation pulses. Transformer isolation ensures that no direct current (DC) is present in the outputs.

- **Channels:** 2 channels are electrically isolated from each other and floating.

Output Specifications:

- Main Pulse duration – 400us
- Main Pulse Shape: Rising and falling Exponential (RC) with a time constant of 50 microseconds
- Main Pulse Frequency 50 to 250 pulses per second (manually adjustable)
- Maximum Main Pulse Intensity: 75V peak-to-peak with 500-Ohm load
- Waveform Ramp Up Time: 2.0 seconds
- Waveform Ramp Down Time: 1.0 seconds
- Output Power - 0.707 watts RMS Max with 500-Ohm load
- Polarity – Waveform polarity can be inverted
- Sensory Waveform Shape: Exponential (RC)
- Sensory Waveform Frequency – 10kHz (fixed)
- Maximum Sensory Waveform Intensity: 14.0V peak-to-peak with 500-Ohm load

Unit Characteristics (*without the stand*):

- **Body:** Plastic
- **Weight:** 1.59kg / 3.5lb

- **Length:** 240mm / 9.45in
- **Width:** 160mm / 6.30in
- **Height:** 40mm / 1.57in

Power Supply

- +12Vdc, 3A, AC to DC power supply. P/N: PEAMD36-12-B2

Electromagnetic Compatibility (EMC)

The NXPRO has been tested for EMC Class B emissions per IEC 60601-1-2:2014. The NXPRO is suitable for use in any establishment, including a private dwelling and a place connected directly to the low voltage mains, which powers residential buildings. Please observe the following precautions when operating the NXPRO.

- Operation in close proximity to shortwave or microwave therapy may produce instability in the output of the device.
- Simultaneous connection to high-frequency surgical equipment may result in burns at the site of stimulator electrodes and possible damage to the device.
- To ensure proper use and to mitigate the possibility of interference, avoid placing in close proximity to other electromagnetic devices.

Maximum Output Voltage & Power vs. Load Resistance

Load Resistance	Output Voltage	Watt RMS to Load
500 ohm	18.8 Vrms	0.707W
2 Kohm	33.7 Vrms	0.568W
10 Kohm	45.5 Vrms	0.207W

Principles of Operation

The principle of electrostimulation is to stimulate nerve fibers by means of electrical impulses transmitted by electrodes. Neuromuscular Electrical Stimulation (NMES) is applied to the muscles and specifically targets the motor nerve with electrical pulses that can activate the junction between the nerves and muscles being treated and produce a contraction of the muscle fibers. A stimulation-induced contraction can give an effective workout for the muscle. The electrical pulses generated by the NXPRO stimulator are high quality pulses - offering safety,

comfort and efficiency. The quantity and the benefits obtained depend on the stimulation parameters.

Non-Clinical Performance Testing

Performance testing consisted of bench testing that has demonstrated that the output of the NeuX NXPRO Neuromuscular Electrical Stimulation Device provided the same performance characteristics as the predicate device. The system successfully passed all tests required by IEC 60601-1, 3rd Edition.

Non-clinical Safety Tests

The NeuX NXPRO Neuromuscular Electrical Stimulation Device has been designed and constructed to meet the following electrical and mechanical safety standards:

- IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (3rd edition)
- IEC 60601-1-2: Medical electrical equipment – Part 1-2: General requirements for safety and essential performance – Collateral Standard: Electromagnetic disturbances – requirements and tests
- IEC 60601-1-11: 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 60601-2-10: Medical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators

There are no significant functional differences between the NXPRO Neuromuscular Electrical Stimulation Device and the ARP POV Sport Device. In accordance with FDA recommended guidance, NeuX Technologies has provided a detailed comparison of the NXPRO

Neuromuscular Electrical Stimulation Device versus the previously cleared ARP POV Sport Device in Tables 5.1 and 5.2.

Table 5.1 - Comparison (Basic Device Characteristics)

Device Name	NXPRO Device	Predicate ARP Sport	Equivalency Discussion
510(k) Number	-	K093999	-
Device Name, Model	NXPRO	POV Sport	-
Manufacturer	NeuX Technologies	Arp Manufacturing	-
Product Code	NGX	NGX	Identical
Regulation	890.5850	890.5850	Identical
Device Class	2	2	Identical
Indications For Use	The NeuX NXPRO Neuromuscular Electrical Stimulation Device is intended for the stimulation of healthy muscles in order to improve or facilitate muscle performance. The NeuX NXPRO is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. The NeuX NXPRO is not designed for use on injured or ailing muscles and its use on such muscles is contraindicated. The NeuX NXPRO's electrical impulses allow triggering action potential on motor	The ARP POV Sport is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The ARP POV Sport is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. The ARP POV Sport is not designed for use on injured or ailing muscles and its use on such muscles is contraindicated. The POV Sport's electrical impulses allow triggering action potential on motor neurons of	Equivalent

Device Name	NXPRO Device	Predicate ARP Sport	Equivalency Discussion
	neurons of motor nerves (excitations). These excitations of motor neurons are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, & total session duration), different types of muscle work can be imposed on the stimulated muscles. The various types of muscle work that the NeuX NXPRPO can impose on the stimulated muscles are able to improve or facilitate muscle performance. The NeuX NXPRO is considered a technique of muscle training.	Motor nerves (excitations). These excitations of motor neurons are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different types of muscle work can be imposed on the stimulated muscles. The various types of muscle work that the POV Sport can impose on the stimulated muscles are able to improve or facilitate muscle performance. The POV Sport is considered a technique of muscle training.	
Power Source(s)	External DC Power Supply	Not Publically Available	Equivalent
- Method of Line Current Isolation	Power Supply Isolation	Not Publically Available	Identical
- Patient Leakage Current	<100μA	Not Publically Available	Identical
- Normal condition	<100μA	Not Publically	Identical

Device Name	NXPRO Device	Predicate ARP Sport	Equivalency Discussion
		Available	
- Single fault condition	<100μA	Not Publically Available	Identical
Number of Output Modes	2	Not Publically Available	Identical
Number of Output Channels	2	Not Publically Available	Identical
- Synchronous or Alternating?	Synchronous	Not Publically Available	Identical
- Method of Channel Isolation	Isolation Transformer	Not Publically Available	Identical
Regulated Current or Regulated Voltage?	Voltage	Not Publically Available	Identical
Software/Firmware/Microprocessor Control?	Yes	Not Publically Available	Equivalent
Automatic Overload Trip?	Yes	Not Publically Available	Identical
Automatic No-Load Trip?	No	Not Publically Available	Identical
Automatic Shut Off?	Yes	Not Publically Available	Equivalent
Patient Override Control?	Yes	Not Publically Available	Equivalent
Indicator Display:	Yes	Not Publically Available	Equivalent
- On/Off Status?	Yes	Not Publically Available	Equivalent
- Low Battery?	N/A (No Batt)	Not Publically Available	NXPRO does not have a battery
- Voltage/Current Level?	Intensity Level (0 to 100%)	Not Publically Available	Equivalent
Timer Range (minutes)	1 to 20 minutes	Not Publically Available	Equivalent

Device Name	NXPRO Device	Predicate ARP Sport	Equivalency Discussion
Compliance with Voluntary Standards?	IEC 60601-1 (3rd Ed) IEC 60601-1-11 IEC 60601-2-10 EN ISO 14971	Not Publically Available	Equivalent Note: IEC 60601-1-4 was withdrawn (IEC 60601-1-11 is the replacement standard)
Compliance* with 21 CFR 898? (*Becomes mandatory beginning May 9, 2000)	Yes	Not Publically Available	Identical
Weight	3.0lb	Not Publically Available	Equivalent
Dimensions (in.) [W x H x D]	10”x7”x2”	Not Publically Available	Equivalent
Housing Materials and Construction	Plastic Injection Molding	Not Publically Available	Identical

Table 5.2 – Comparison (Output Specifications)

Device Name	NXPRO Device	Predicate ARP Sport	Equivalency Discussion
Waveform (e.g., pulsed monophasic, biphasic)	Asymmetric biphasic	Not Publically Available	Identical
Shape (e.g., rectangular, spike, rectified sinusoidal)	Rectangular	Not Publically Available	Identical
Maximum Output Voltage (specify units)	18.8Vrms @ 500 Ω	Not Publically Available	Equivalent
(+/- 5%)	33.7Vrms @ 2 kΩ	Not Publically Available	Equivalent
	45.5Vrms @ 10 kΩ	Not Publically Available	Equivalent
Maximum Output Current (specify units)	37.6 mArms @ 500 Ω	Not Publically Available	Equivalent
(+/- 5%)	16.9 mArms @ 2 kΩ	Not Publically Available	Equivalent

Device Name	NXPRO Device	Predicate ARP Sport	Equivalency Discussion
	4.6 mArms @ 10 kΩ	Not Publically Available	Equivalent
Pulse Width (specify units)	314 microseconds	Not Publically Available	Equivalent
Frequency (Hz)	Main: 50-250pps. Background: 10kHz	Not Publically Available	Equivalent
For interferential modes only:	N/A	Not Publically Available	-
- Beat Frequency (Hz)	N/A	Not Publically Available	-
For multiphasic waveforms only:			
- Symmetrical phases?	No	Not Publically Available	Identical
- Phase Duration (include units) (state range, if applicable) (both phases, if asymmetrical)	N/A	Not Publically Available	-
Net Charge (mC per pulse) (If zero, state method of achieving zero net charge.)	0 mC @ 500 Ω Output is AC coupled via isolation transformers to result in zero net charge.	Not Publically Available	Equivalent
Maximum Phase Charge, (mC)	11.8 uC @ 500 Ω	Not Publically Available	Equivalent
Maximum Current Density, (mA/cm²)	1.46 mA/cm² @ 500 Ω	Not Publically Available	Equivalent
Maximum Power Density, (W/cm²) (using smallest electrode conductive surface area)	2.15 mW/cm² @ 500 Ω	Not Publically Available	Equivalent
Burst Mode (i.e., pulse trains) a. Pulses per burst b. Bursts per second c. Burst duration (seconds) d. Duty Cycle [Line (b) x Line (c)]	'Intermittent' Mode: 50 to 250 pulses/burst 1 burst/second 0 to 60 second duration 0 to 100%	Not Publically Available	Equivalent
ON Time (seconds)	0 to 60 seconds	Not Publically Available	Equivalent
OFF Time (seconds)	0 to 60 seconds	Not Publically	Equivalent

Device Name	NXPRO Device	Predicate ARP Sport	Equivalency Discussion
		Available	
Additional Features (if applicable)	N/A	Not Publically Available	-

Conclusion Statement

The NeuX NXPRO – Neuromuscular Electrical Stimulation Device has the same intended use as the predicate device (ARP POV Sport). Any minor technological differences to the device do not raise new questions of safety or effectiveness. Performance testing, along with verification and validation activities demonstrate that the NeuX NXPRO – Neuromuscular Electrical Stimulation Device is as safe and effective in its intended use, and performs as well as the predicate device. Therefore, the NeuX NXPRO – Neuromuscular Electrical Stimulation Device can be considered substantially equivalent to the ARP Manufacturing POV Sport Device.