June 11, 2021

NeuraLace Medical, Inc.
% Allison Komiyama
Principal Consultant
AcKnowledge Regulatory Strategies LLC
2251 San Diego Ave, Suite B-257
San Diego, California 92121

Re: K210021
Trade/Device Name: Axon Therapy
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief.
Regulatory Class: Class II
Product Code: QPL, IPF
Dated: May 10, 2021
Received: May 11, 2021

Dear Allison Komiyama:

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,

Jitendra Virani
Acting 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)*
K210021

Device Name
Axon Therapy

Indications for Use *(Describe)*
The Axon Therapy is intended to stimulate peripheral nerves for relief of chronic intractable, post-traumatic and post-surgical pain for patients 18 and older.

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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510(k) Summary

K210021

DATE PREPARED

June 11, 2021

MANUFACTURER AND 510(k) OWNER

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DEVICE INFORMATION

Proprietary Name/Trade Name:	Axon Therapy
Common Name:	Electromagnetic stimulator, pain relief
Regulation Number:	21 CFR 882.5890
Regulation Name:	Transcutaneous electrical nerve stimulator for pain relief
Class:	Class II
Primary Product Code:	QPL
Secondary Product Code:	IPF
Premarket Review:	Neurological and Physical Medicine Devices (OHT5) Neuromodulation and Physical Medicine Devices (DHT5B)
Review Panel:	Neurology Physical Medicine

PREDICATE DEVICE IDENTIFICATION

The Axon Therapy is substantially equivalent to the following predicate:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K181688	R-C1 TENS and EMS Stimulator; R-E1 EMS Stimulator; R-T1 TENS Stimulator / Shenzhen Roundwhale Technology Co., Ltd.	✓
K973929	MS-101 Magnetic Muscle Stimulator System / Neotonus, Inc.	(Reference Device)
K160280	MagPro R20 / Tonica Elektronik A/S	(Reference Device)

The predicate device has not been subject to a design related recall.

DEVICE DESCRIPTION

The Axon Therapy is a magnetic stimulator system that provides brief and focused magnetic pulses in order to non-invasively stimulate peripheral nerves and provide chronic nerve pain relief. The subject device is intended to be used in clinics such as pain management clinics and physical therapy clinics. The device consists of Magnetic Stimulator, Stimulation Coil, Liquid Cool Unit, and a Cart. The Axon Therapy includes a thermal shutdown feature which is activated once the inside temperature of the stimulation coil either: (A) reaches 45°C or (B) exceeds 41°C for a total of nine minutes during a 20-minute session.

INDICATIONS FOR USE

The Axon Therapy is intended to stimulate peripheral nerves for relief of chronic intractable, post-traumatic and post-surgical pain for patients 18 and older.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

NeuraLace believes that the Axon Therapy is substantially equivalent to the predicate device based on the information summarized here:

The subject device has a similar design and dimensions and uses similar or identical materials as the device cleared in K181688. The subject device has the same intended use and similar technological characteristics (i.e., nerve stimulation for relief of chronic intractable pain) to the devices cleared in K181688, K973929, and K160280. These technological characteristics have undergone testing to ensure the device is as safe and effective as the predicate.

510(k) Summary

	Subject Device	***Predicate Device***	***Reference Device***	***Reference Device***	***Statement of Equivalence***
	NeuraLace Medical, Inc. Axon Therapy	Shenzhen Roundwhale Technology Co., Ltd. R-C1 TENS and EMS Stimulator; R-E1 EMS Stimulator; R-T1 TENS Stimulator K181688	Neotonus, Inc. MS-101 Magnetic Muscle Stimulator System K973929	Tonica Elektronik A/S MagPro R20 K160280	
Indications for Use	The Axon Therapy is intended to stimulate peripheral nerves for relief of chronic intractable, post-traumatic and post-surgical pain for patients 18 and older.	R-C1 TENS and EMS Stimulator For TENS mode: 1. Symptomatic relief of chronic intractable pain; 2. Post traumatic pain; 3. Post surgical pain; For EMS mode: 1. Relaxation of muscle spasm; 2. Increase of local blood flow circulation; 3. Prevention or retardation of disuse atrophy; 4. Muscle re-education; 5. Maintaining or increasing range of motion; 6. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis. R-E1 EMS Stimulator: 1. Relaxation of muscle spasm; 2. Increase of local blood flow circulation; 3. Prevention or retardation of disuse atrophy; 4. Muscle re-education; 5. Maintaining or increasing range of motion; 6. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis. R-T1 TENS Stimulator: 1. Symptomatic relief of chronic intractable pain; 2. Post traumatic pain; 3. Post surgical pain.	The Neotonus MS-101 Magnetic Muscle Stimulator System is intended to be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions. The Neotonus MS-101 is indicated for use in stimulating neuromuscular tissues for bulk muscle excitation in the legs anor arms for rehabilitative purposes. Indications for Use for Muscle Stimulators: Relaxation of muscle spasms Prevention or retardation of disuse atrophy Increasing local blood circulation Muscle re-education Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis Maintaining or increasing range of motion	MagPro R20 is intended to be used for stimulation of peripheral nerves for diagnostic purposes	Substantially equivalent to the predicate device. Clinical and performance testing demonstrate that there is no impact on safety and effectiveness.

510(k) Summary

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	NeuraLace Medical, Inc. Axon Therapy	Shenzhen Roundwhale Technology Co., Ltd. R-C1 TENS and EMS Stimulator; R-E1 EMS Stimulator; R-T1 TENS Stimulator K181688	Neotonus, Inc. MS-101 Magnetic Muscle Stimulator System K973929	Tonica Elektronik A/S MagPro R20 K160280	
Product Codes / Regulation Number	QPL / 21 CFR 882.5890 IPF / 21 CFR 890.5850	GZJ / 21 CFR 882.5890 IPF / 21 CFR 890.5850	IPF / 21 CFR 890.5850	GWF / 21 CFR 882.1870	The regulation is identical to the predicate device. QPL is a new product code that was generated due to product design differences. No impact on safety and effectiveness.
Technological Characteristics					
Power source	Power Supply: 110V to 240V ac, 50/60Hz Power consumption: 800VA maximum, 115W idle	4x AAA Batteries	Unknown	Power Supply via Isolation Transformer Power Supply: 120V~, 50/60 Hz. Power consumption: Maximum 800VA	Substantially equivalent to the predicate device. ES testing demonstrates there is no impact on safety and effectiveness.
User Interface	LED display	LCD display	Unknown	Intensity display (coil temperature, intensity) Menu display and indicators	Substantially equivalent to the predicate device. No impact on safety and effectiveness.
Output channels	N/A	2 alternating channels	Unknown	Unknown	This feature is not applicable to the subject device. Performance and clinical data demonstrate that there is no impact on safety and effectiveness.
Number of treatment programs	N/A	12 TENS, 9 EMS	Unknown	Unknown	This feature is not applicable to the subject device. Performance and clinical data demonstrate that there is no impact on safety and effectiveness.
Waveform	Biphasic wave	Biphasic square	Unknown	Biphasic wave	Identical to the reference device. Performance and clinical data demonstrate that there is no impact on safety and effectiveness when compared to the predicate device.
Constant current or constant voltage?	N/A	Constant current	Unknown	Unknown	This feature is not applicable to the subject device. ES and EMC testing demonstrate that there is no impact on safety and effectiveness.

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Software/Firmware/ Microprocessor Control?	Yes	Yes	Unknown	Unknown	Identical to the predicate device. No impact on safety and effectiveness.
Indication functions	On/off status Ready status	On/off status Low battery Voltage/current level	Unknown	Unknown	Substantially equivalent to the predicate device. No impact on safety and effectiveness.
Time range	800 seconds (400 pulses at 0.5 Hertz)	Nonadjustable 28, 30 and 32 minutes	Unknown	Unknown	Substantially equivalent to the predicate device. Clinical and performance testing demonstrate that there is no impact on safety and effectiveness.
Patient Leakage Current	N/A	Normal condition: 11.4 µA Single fault condition: 9.6 µA	Unknown	Unknown	This feature is not applicable to the subject device. ES and EMC testing demonstrate that there is no impact on safety and effectiveness.

510(k) Summary

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Housing materials construction	Stimulator: AL sheet EN AW 5754 H111 Coil: ABS	Plastic (ABS) enclosure	Unknown	Unknown	Substantially equivalent to the predicate device. Biocompatibility, electrical safety, and clinical testing demonstrate that there are no new questions of safety and effectiveness.
Applied part(s)	Coil 60BF-NL	Electrode pad	C-shaped magnetic coil	Compatible coils: Static cooled coils (MCF-B65, MCF-125, MCF-B70) Non-cooled coils (C-100, C-B60, MMC-140-II, RT-120-II)	Substantially equivalent to the predicate device. Performance and clinical testing demonstrate that there are no new questions of safety and effectiveness.
Applied part area	16 cm^2	25 cm^2	Unknown	Circular coils: ø110-126 mm Butterfly coils: 2x75 mm, 2x96 mm Special coils: ø80x160 mm	Substantially equivalent to the predicate device. Performance and clinical testing demonstrate that there are no new questions of safety and effectiveness
Treatment area	Any area, such as Hand, Arm, Chest, Waist, Buttock, Thigh, Calf, Back and low back etc.	Any area, such as Hand, Arm, Chest, Waist, Buttock, Thigh, Calf, Back and low back etc.	Unknown	Unknown	Identical to the predicate device. No impact on safety and effectiveness.
Weight	Stimulator: 17 kg Coil: 3.2 kg Full system (with cart): 54 kg	0.243 lbs	Unknown	44 lbs (20 kg)	Substantially equivalent to the predicate device. Device weight will have little to no impact on safety and effectiveness.
Unit Dimensions	485 x 380 x 165 mm	2.78x 4.82x 1.08 in (HxWxD)	Unknown	5.9x15.3x17.3 in (HxWxD)	Substantially equivalent to the predicate device. Unit dimensions will have little to no impact on safety and effectiveness.
Pulse frequency	0-2 Hz	Unknown	1-55 Hz	0-22 Hz	Similar to the reference devices. Performance and clinical testing demonstrate that there are no new questions of safety and effectiveness when compared to the predicate device.

510(k) Summary

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Pulse amplitude	0 to 100% A maximum of 80% intensity is recommended to reduce the risk of coil overheating	Unknown	0-100%	0-100%	Identical to the reference devices. Performance and clinical testing demonstrate that there are no new questions of safety and effectiveness when compared to the predicate device.
On-cycle duty period	2-800 seconds	Unknown	1-30 seconds	Unknown	Similar to the reference device. Performance and clinical testing demonstrate that there are no new questions of safety and effectiveness when compared to the predicate device.
Off-duty rest period	N/A	Unknown	0-60 seconds	Unknown	Similar to the reference device. Performance and clinical testing demonstrate that there are no new questions of safety and effectiveness when compared to the predicate device.
Maximum repetition rate	2 pulses per second (pps)	Unknown	Unknown	20 pulses per second (pps)	Similar to the reference device. Performance and clinical testing demonstrate that there are no new questions of safety and effectiveness when compared to the predicate device.
Pulse mode	Standard	Unknown	Unknown	Standard	Identical to reference device. Performance and clinical testing demonstrate that there are no new questions of safety and effectiveness when compared to the predicate device.

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	NeuraLace Medical, Inc. Axon Therapy	Shenzhen Roundwhale Technology Co., Ltd. R-C1 TENS and EMS Stimulator; R-E1 EMS Stimulator; R-T1 TENS Stimulator K181688	Neotonus, Inc. MS-101 Magnetic Muscle Stimulator System K973929	Tonica Elektronik A/S MagPro R20 K160280	
Pulse width	Biphasic (290 µsec)	Unknown	Unknown	Biphasic (280 µsec)	Identical to reference device. Performance and clinical testing demonstrate that there are no new questions of safety and effectiveness when compared to the predicate device.
Maximum output power	100% at 2 pps	Unknown	Unknown	100% at 5 pps 75% at 10 pps 40% at 15 pps 35% at 20 pps	Similar to the reference device. Performance and clinical testing demonstrate that there are no new questions of safety and effectiveness when compared to the predicate device.
Testing					
Non-Clinical Testing	Electrical safety per IEC 60601-1 EMC testing per IEC 60601-1-2 Software testing per IEC 62304 Usability testing per IEC 62366-1	Performance testing per IEC 60601-2-10 Electrical safety per IEC 60601-1 and IEC 60601-1-11 (home use standard) EMC testing per IEC 60601-1-2 Software testing per IEC 62304 Usability testing per IEC 62366-1	Unknown	Electrical safety per IEC 60601-1 EMC testing per IEC 60601-1-2	Substantially equivalent to the predicate device. Performance and clinical testing demonstrate that there are no new questions of safety and effectiveness.
Clinical Testing	Three studies that evaluated the effectiveness and safety of the subject device.	None	Comparative study of the physiological effect of the MS-101 and the predicate on the knee extensor muscles of 9 healthy volunteers	None	Substantially equivalent to the predicate device. Performance and clinical testing demonstrate that there are no new questions of safety and effectiveness.

SUMMARY OF NON-CLINICAL TESTING

The following tests were performed to demonstrate safety based on current industry standards:

Software Verification: The software development and testing were executed in compliance to IEC 62304:2006 *Medical device software - Software life cycle processes*

Electromagnetic Compatibility and Electrical Safety: The subject device was tested in compliance to:

- IEC 60601-1:2005+AMD1:2012 CSV *Consolidated version, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
- IEC 60601-1-2 Edition 4.0 2014-02 *Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests*
- IEC 60601-1-8 Edition 2.1 2012-11 *Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

Usability: The subject device was tested in compliance to:

- IEC 60601-1-6 Edition 3.1 2013-10 *Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability*
- IEC 62366:2007+AMD1:2014 CSV *Medical devices - Application of usability engineering to medical device*

Performance Testing: The subject device underwent the following performance testing:

- Cleaning validation
- Packaging validation
- Magnetic field characteristic measurements and stimulation model
- Stimulation protocol accuracy validation
- Temperature on surface at maximum output validation
- Magnetic field model and measurement comparison

SUMMARY OF CLINICAL TESTING

NeuraLace conducted multiple clinical studies to assess the safety and effectives of the Axon Therapy in subjects with post-traumatic or post-surgical neuropathic pain. All subjects (n=105) were evaluated for pain prior to and after device use using the numeric rating scale (NRS) or the Mechanical Visual Analog Scale (MVAS). Twenty-five of 105 subjects underwent three consecutive sessions within one week and were asked to rate their pain after the session, one week, and one month later. All subjects had a statistically significant decrease in their pain

score. The remaining subjects followed a 12-week schedule (a total of nine sessions). Pain levels were assessed multiple times throughout the study: prior to study commencement, after the first three sessions, after session 6, after session 8, and after session 9 using the MVAS. After 12 weeks, all subjects had a decreased MVAS score, highlighting the effectiveness of the subject device. During the studies, two non-serious adverse events related to device use occurred: hypersensitivity (n=3) and muscle soreness (n=5). These adverse events are the same or similar to the adverse events associated with the predicate TENS device. Furthermore, unlike the predicate device, Axon Therapy does not result in burn marks, skin irritation, or analgesic tolerance, highlighting the safety benefit of the subject device.

CONCLUSION

Based on the testing performed, including clinical testing, software validation, electrical safety testing, and performance testing, it can be concluded that the subject device does not raise new issues of safety and effectiveness compared to the predicate device. The similar indications for use, technological characteristics, and performance characteristics for the proposed Axon Therapy are assessed to be substantially equivalent to the predicate device supported by the performance data discussed above.