



January 10, 2024

NeuraLace Medical Inc.
% Allison Komiyama, PhD, RAC
VP, MedTech Innovation
RQM+
2251 San Diego Ave,
Suite B-257
San Diego, California 92110

Re: K233364

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: September 29, 2023
Received: October 2, 2023

Dear Dr. 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 (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.

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,

Lauren E. Woodard -S

for Amber Ballard, Ph.D.

Assistant Director

DHT5B: Division of Neuromodulation

and Rehabilitation Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K233364

Device Name
Axon Therapy

Indications for Use (Describe)

The Axon Therapy is intended to stimulate peripheral nerves for relief of chronic intractable pain, post-traumatic pain, post-surgical pain and/or for relief of chronic painful diabetic peripheral neuropathy in the lower extremities. The Axon Therapy is for use on 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.

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

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510(k) SUMMARY
K233364

DATE PREPARED

January 10, 2024

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
Product Code: QPL
IPF
Review Panel: Neurology
Physical Medicine

PREDICATE DEVICE IDENTIFICATION

The Axon Therapy is substantially equivalent to the following predicates:

<i>510(k) Number</i>	<i>Predicate Device Name / Manufacturer</i>	<i>Primary Predicate</i>
K210021	Axon Therapy / NeuraLace	✓

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 pain, post-traumatic pain, post-surgical pain and/or for relief of chronic painful diabetic peripheral neuropathy in the lower extremities. The Axon Therapy is for use on 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 an identical design and dimensions, and uses identical materials as the device cleared in K210021. The subject device has the same intended use and identical technological characteristics to the device cleared in K210021. The device has identical instrumentation to the device cleared in K210021.

Comparison Topic	Subject Device	Predicate Device	Statement of Equivalence
Company Name / Device Name	NeuraLace Medical Inc. Axon Therapy	NeuraLace Medical Inc. Axon Therapy	N/A
Indications for Use	The Axon Therapy is intended to stimulate peripheral nerves for relief of chronic intractable pain, post-traumatic pain, post-surgical pain and/or for relief of chronic painful diabetic peripheral neuropathy in the lower extremities. The Axon Therapy is for use on patients 18 and older.	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.	Substantially equivalent to the predicate device. Clinical testing demonstrates that there is no impact on safety and effectiveness for expanded indication.
Product Codes / Regulation Numbers	QPL / 21 CFR 882.5890 IPF / 21 CFR 890.5850	QPL / 21 CFR 882.5890 IPF / 21 CFR 890.5850	Identical to predicate device with no impact on safety and effectiveness.
Technological Characteristics			
Power Source	Power Supply: 110V to 240V ac, 50/60Hz Power consumption: 800VA maximum, 115W idle	Power Supply: 110V to 240V ac, 50/60Hz Power consumption: 800VA maximum, 115W idle	Identical to predicate device with no impact on safety and effectiveness.

Comparison Topic	Subject Device	Predicate Device	Statement of Equivalence
Company Name / Device Name	NeuraLace Medical Inc. Axon Therapy	NeuraLace Medical Inc. Axon Therapy	N/A
User Interface	LED display	LED display	Identical to predicate device with no impact on safety and effectiveness.
Waveform	Biphasic wave	Biphasic wave	Identical to predicate device with no impact on safety and effectiveness.
Software / Firmware / Microprocessor Control?	Yes	Yes	Identical to predicate device with no impact on safety and effectiveness.
Indication Functions	On/off status Ready status	On/off status Ready status	Identical to predicate device with no impact on safety and effectiveness.
Time Range	800 seconds (400 pulses at 0.5 Hertz)	800 seconds (400 pulses at 0.5 Hertz)	Identical to predicate device with no impact on safety and effectiveness.
Housing Materials Construction	Stimulator: AL sheet EN AW 5754 H111 Coil: ABS	Stimulator: AL sheet EN AW 5754 H111 Coil: ABS	Identical to predicate device with no impact on safety and effectiveness.
Applied Part(s)	Coil 60BF-NL	Coil 60BF-NL	Identical to predicate device with no impact on safety and effectiveness.
Applied Part Area	16 cm ²	16 cm ²	Identical to predicate device with no impact on 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.	Identical to predicate device with no impact on safety and effectiveness.
Weight	Stimulator: 17 kg Coil: 3.2 kg Full system (with cart): 54 kg	Stimulator: 17 kg Coil: 3.2 kg Full system (with cart): 54 kg	Identical to predicate device with no impact on safety and effectiveness.
Unit Dimensions	485 x 380 x 165 mm	485 x 380 x 165 mm	Identical to predicate device with no impact on safety and effectiveness.
Pulse Frequency	0-2 Hz	0-2 Hz	Identical to predicate device with no impact on safety and effectiveness.
Pulse Amplitude	0 to 100% A maximum of 80% intensity is recommended to reduce the risk of coil overheating	0 to 100% A maximum of 80% intensity is recommended to reduce the risk of coil overheating	Identical to predicate device with no impact on safety and effectiveness.
On-Cycle Duty Period	2-800 seconds	2-800 seconds	Identical to predicate device with no impact on safety and effectiveness.
Maximum Repetition Rate	2 pulses per second (pps)	2 pulses per second (pps)	Identical to predicate device with no impact on safety and effectiveness.
Pulse Mode	Standard	Standard	Identical to predicate device with no impact on safety and effectiveness.

Comparison Topic	Subject Device	Predicate Device	Statement of Equivalence
Company Name / Device Name	NeuraLace Medical Inc. Axon Therapy	NeuraLace Medical Inc. Axon Therapy	N/A
Pulse Width	Biphasic (290 µsec)	Biphasic (290 µsec)	Identical to predicate device with no impact on safety and effectiveness.
Maximum Output Power	100% at 2 pps	100% at 2 pps	Identical to predicate device with no impact on safety and effectiveness.
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	Electrical safety per IEC 60601-1 EMC testing per IEC 60601-1-2 Software testing per IEC 62304 Usability testing per IEC 62366-1	Identical to predicate device, no new elements proposed for subject device requiring new non-clinical testing. No impact to safety and effectiveness.
Clinical Testing	Three previous studies that evaluated the effectiveness and safety of the subject device. One additional study for patients with diabetic peripheral neuropathy (PDN) for the subject device.	Three studies that evaluated the effectiveness and safety of the subject device.	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 Axon Therapy subject device had no design changes from the predicate device cleared in K210021 that required additional non-clinical testing for this submission to demonstrate safety and effectiveness:

Software Verification: The subject device did not undergo any new software verification testing due to substantial equivalence of the predicate device and no new questions of safety and effectiveness.

Electromagnetic Compatibility and Electrical Safety: The subject device did not undergo any new electromagnetic compatibility and electrical safety testing due to substantial equivalence of the predicate device and no new questions of safety and effectiveness.

Usability: The subject device did not undergo any new usability testing due to substantial equivalence of the predicate device and no new questions of safety and effectiveness.

Performance Testing: The subject device did not undergo any new performance testing due to substantial equivalence of the predicate device and no new questions of safety and effectiveness.

SUMMARY OF CLINICAL TESTING

The goal of the Axon Therapy PDN clinical study was to expand the indications to include painful diabetic peripheral neuropathy. Axon Therapy was demonstrated to be effective and safe in the original clinical studies for chronic intractable post-traumatic and post-surgical pain. The primary efficacy objective of this trial was to compare the proportion of responders in the Axon Therapy plus CMM group, (responder is defined as a subject who experiences 50% or greater reduction from baseline in neuropathic pain intensity as measured by an in-clinic visual analog score (VAS) for the primary area of pain at Day 30, with no increase over baseline pain medications within four weeks of the Day 30 visit), to the Sham plus CMM group.

The results of the study demonstrate effectiveness of this non-invasive Treatment at statistically significant levels. The % reduction in VAS pain scores showed a -57.6% reduction for Treatment vs -12.5% for Sham at a p value of <0.00001. The -45.1% VAS pain reduction from Sham supports the argument that these are statistically significant improvements in patient care and not a placebo effect. In addition to pain relief, both the QoL-DN and PGIC scales show that this pain relief manifests into better quality of life outcomes at a statistically significant level.

CONCLUSION

The Axon Therapy is considered substantially equivalent to the predicate device based on the testing performed, the similar indications for use, and identical technological characteristics. Based on the testing performed it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate devices.