June 26, 2025

Neuralytix, LLC
Christopher Wybo
CEO
138 S Park Square
Ste 203
Fruita, Colorado 81521

Re: K243636
Trade/Device Name: Neuralytix iD3 System (NTX-9001)
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: PDQ, ETN
Dated: May 27, 2025
Received: May 27, 2025

Dear Christopher Wybo:

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,

Patrick Antkowiak -S

for
Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic 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)*
K243636

Device Name
Neuralytix iD3 System

Indications for Use *(Describe)*
This device is intended for use in surgical procedures to assist in locating and mapping motor nerves through the use of mechanomyographic (MMG) signals and electrical stimulus of nerves. The device provides information directly to the surgeon to help assess a patient's neurophysiologic status by measuring and comparing MMG signals throughout a surgical procedure.

The device is intended to identify relative changes in the conduction and neural transmission ability of the nerve throughout a surgical procedure by measuring and comparing the minimum amount of electrical stimulation current (mA) required to induce a measurable MMG response (MMG nerve response threshold).
Examples of surgical applications which may require mechanomyographic (MMG) monitoring:

• Minimally invasive and open spinal surgery involving spinal fusion cages, screws, rods, plates, discs and biologics.
• Minimally invasive, open and endoscopic, direct and indirect nerve decompressions, discectomies, laminectomies, laminotomies, facetectomies, foraminotomies.
• Treatment of nerve compression, stenosis, degenerative disc disease, disc herniation, spondylolisthesis.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

A. Submitter Information

Manufacturer/Submitter:	Neuralytix, LLC 138 S Park Square, STE 203 Fruita, CO 81521
Contact Person:	Christopher Wybo (248) 416-0740 wybo@nerve.health

B. Date Prepared

June 24, 2025

C. Device Name

Trade/Proprietary Name:	Neuralytix iD3 System
Common/Usual Name:	Surgical Nerve Stimulator/Locator
Device Classification:	Class II per 21 CFR §874.1820
Product Code/Description:	PDQ; Neurosurgical Nerve Locator ETN; Stimulator, Nerve

D. Predicate Device Name

The subject Neuralytix iD3 System is substantially equivalent to the following primary predicate device:

- K173526 Sentio MMG Gen 2

E. Device Description

The Neuralytix iD3 System is a multichannel device for locating, mapping and assessing the status of motor nerves during surgical procedures. Neuralytix alerts the user of recorded mechanical activity (termed mechanomyography, or MMG) from muscles innervated by affected nerves, which may originate from operator applied electrical stimulus. The device will assist with nerve identification and assessment by alerting the surgeon when monitored nerves are activated. The device will also assist with tracking the status of monitored nerves throughout the course of surgical intervention. Neuralytix is especially useful in helping assess a patient's neurophysiologic status by measuring and identifying nerve response thresholds, or the minimum amount of electrical current (mA) necessary to elicit an MMG response. Neuralytix enables intuitive controls for measuring, recording and comparing nerve response thresholds throughout a surgical procedure to provide insights to the user as to how the conduction and neural transmission ability of a nerve may change throughout surgery.

F. Technological Characteristics

Attribute	Subject Device Neuralytix iD3 System	Predicate Device Sentio MMG Gen 2	Substantially Equivalent
Capital Equipment: Control Unit/Display			
Number of Channels	Max 8	Max 10	Yes
Display Size	20cm x 13cm x 4cm	32cm x 22cm x 3cm	Yes
Weight	0.72 kg	2.0 kg	Yes
Screen Size	7.0 inch	9.8 inch	Yes
System Stimulation			
Type Constant	Constant current (mA)	Constant current (mA)	Yes
Stimulus Range	0-20 mA Standard Mode 0.3-4 mA Hi-Res Mode	0-20 mA Nerve Mapping 0-2 mA Bipolar Mode	Yes
Control	Digitally controlled, adjusted in increments as follows per mode: 1mA Standard Mode 0.1mA Hi-Res Mode	Digitally controlled, adjusted in increments as follows per mode: 1mA Nerve Mapping 0.1mA Bipolar Mode	Yes
Maximum Stimulation Voltage	160V	115V	Yes
Waveform	Monophasic rectangular pulse	Monophasic rectangular pulse	Yes
Pulse Width	100µs	100µs	Yes
Stimulation Rate	4Hz, 8Hz	2Hz, 4Hz	Yes
Sensors			
Function	Mechanomyographic (MMG)	Mechanomyographic (MMG)	Yes
Type	Accelerometer	Accelerometer	Yes
Size	2-inch round	2-inch round	Yes
Ground Patch			
Attachment Mode	Hydrogel Adhesive	Hydrogel Adhesive	Yes
Size	2 x 4 inch	2 x 4 inch	Yes
Connector Type	1.5 mm touchproof	1.5 mm touchproof	Yes
Stimulation Instruments			

Attribute	Subject Device Neuralytix iD3 System	Predicate Device Sentio MMG Gen 2	Substantially Equivalent
Length	200 mm	200 mm	Yes
Stimulation Diameter	2.0 mm	2.2 mm	Yes
Stimulation Surface Area	14.5 mm^2	14.7 mm^2	Yes
Maximum charge density	13.79 uC/cm^2	13.61 uC/cm^2	Yes
Maximum RMS current density	3.9 mA/cm^2	2.72 mA/cm^2	Yes
Maximum power density	22.07 W/cm^2	15.65 W/cm^2	Yes
Electrical Insulation	Parylene C	Parylene C	Yes
Proximal Connector	1.5mm touchproof	1.5mm touchproof	Yes
Patient Contacting Material	316L Stainless Steel; Parylene C	316L Stainless Steel; Parylene C	Yes
Delivery	Sterile via Gamma Radiation; Single Use	Sterile via Ethylene Oxide Radiation; Single Use	Yes

G. Indications for Use/Intended Use

This device is intended for use in surgical procedures to assist in locating and mapping motor nerves through the use of mechanomyographic (MMG) signals and electrical stimulus of nerves. The device provides information directly to the surgeon to help assess a patient's neurophysiologic status by measuring and comparing MMG signals throughout a surgical procedure.

The device is intended to identify relative changes in the conduction and neural transmission ability of the nerve throughout a surgical procedure by measuring and comparing the minimum amount of electrical stimulation current (mA) required to induce a measurable MMG response (MMG nerve response threshold).

Examples of surgical applications which may require mechanomyographic (MMG) monitoring:

- Minimally invasive and open spinal surgery involving spinal fusion cages, screws, rods, plates, discs and biologics.
- Minimally invasive, open and endoscopic, direct and indirect nerve decompressions, discectomies, laminectomies, laminotomies, facetectomies, foraminotomies.
- Treatment of nerve compression, stenosis, degenerative disc disease, disc herniation, spondylolisthesis.

H. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use

Attribute	Substantial Equivalence Evaluation
Indications for Use	The indications for use statement of the subject device is substantially equivalent to the primary predicate device, with additional language provided for clarifying how the device is used intraoperatively and what MMG signals are measured and recorded for helping surgeons assess a patient's neurophysiological status. The clarifying language and differences in indications for use do not change the intended use as a surgical nerve stimulator / locator, nor raise new questions of safety or effectiveness, as demonstrated by results of the risk-based verification and validation testing.
Capital Equipment: Control Unit/Display	Sensor Channel Display - Live streaming graphs for each sensor channel is substantially equivalent to the predicate device. Stimulation Output Display - Real time display of active stimulation current (mA) is substantially equivalent to the predicate device. Alerts - Substantially equivalent - Subject device meets the same acceptance criteria and conforms to the same consensus standards as the primary predicate device for visually and audibly alerting the user of device activity. User Interface - Touchscreen graphical user interface control is substantially equivalent to the predicate device. Display Size - Substantially equivalent - Subject device meets the same acceptance criteria and conforms to the same consensus standards as the primary predicate device for displaying relevant and critical device information to the user on the touchscreen display. Weight - Substantially equivalent - Subject device meets the same acceptance criteria and conforms to the same consensus standards as the primary predicate device.
Event Detection Algorithm	Enhanced signal acquisition and MMG event detection is substantially equivalent to the predicate device, as evidenced by the comparative performance evaluation.
System Stimulation	Stimulation Output – Cathodic constant current (mA) stimulation output via rectangular waveform pulse is substantially equivalent to the predicate device. Stimulus Range - Standard (0-20 mA) and Hi-Res (0.3-4 mA) stimulation ranges are substantially equivalent to the predicate device and have the same intended function. Stimulation Pulse Width – Substantially equivalent to the predicate device. Stimulation Pulse Rate - User selectable and continuous; substantially equivalent to the predicate device.

	Control - Digitally controlled, incremental adjustment for Standard (0-20 mA in 1 mA increments) and Hi-Res (0.3-4 mA in 0.1 mA increments) stimulation modes via touchscreen display is substantially equivalent to the predicate device. Maximum Stimulation Voltage - Maximums are within the limit settings and substantially equivalent to the predicate device.
Stimulation Instruments	Substantially equivalent to predicate device in terms of conductive materials, dielectric properties, exposed stimulation surface areas and intended function.
Sensors	Signal (electromechanical) - same as predicate device. Technology - Digital, same as predicate device. Configuration - 4-channels per harness/connector, simplified usability while substantially equivalent performance requirements as predicate device. Usability - Increased robustness for multi-use applications; substantially equivalent performance requirements as predicate device. Size - substantially equivalent to predicate device. Connector Type - Simplified for usability, substantially equivalent performance requirements as predicate device. Operating Voltage - 1.8V; substantially equivalent to predicate device.
Sensor Patches	Single-use sensor patches configured for application with multi-use sensor harness. Substantially equivalent size, materials and intended function and performance requirements as predicate device for adhering sensors to patient.
Ground Patch	Substantially equivalent size, materials, biocompatibility and performance requirements as predicate device.
Materials	All components are comprised of materials evidenced to be suited for their intended purpose, with applicable biocompatible components and intended function substantially equivalent to the predicate device.

I. Materials / Contact Classification

The contact classification for the patient contacting components of the NTX-9003 Decompression Stim Probe is externally communicating with tissue/bone and cerebrospinal fluid contact for a limited duration (<= 24 hours). The patient contacting materials of the subject device are biocompatible 316L stainless steel with Parylene C conformal coating.

The contact classification for the patient contacting components of the Sensor Patch and Ground Patch (NTX-9004/NTX-9004) is skin contacting for a limited duration (<= 24 hours). The patient contacting material of the subject device is biocompatible hydrogel adhesive.

J. Biocompatibility

A Biocompatibility Evaluation was performed on the Neuralytix iD3 System to support the Substantial Equivalence. A Summary of Biocompatibility Testing is provided below

NTX-9003, iD3 Decompression Stim Probe: Biocompatibility Testing performed on the subject device; NTX-0301, iD3 Decompression Stim Probe

Test	Results	Conclusions
Cytotoxicity – MEM Elution	No cytotoxicity or cell lysis was noted in any of the test wells. No pH shift was observed at 48 hours. The reagent control, negative control and the positive control performed as anticipated.	Non-Cytotixic
Sensitization – GPMT	All animals were observed with the expected dermal reactions associated with intradermal injection of FCA and were clinically normal throughout the study. No evidence of sensitization was observed.	Non-sensitizer
Intracutaneous Reactivity	All animals appeared normal throughout the study. All injection sites appeared normal immediately following injection. No difference was noted between the Test and Control means.	Non-Irritant
Acute Systemic Toxicity	There was no mortality or evidence of systemic toxicity from the extracts injected into mice. Each test article extract met the requirements of the study.	Non-Toxic
Material-Mediated Pyrogenicity, USP-Rabbit	No single animal showed a temperature rise of 0.5°C or more above its baseline temperature. The total rise of the rabbits' temperature during 3 hours was 0.0°C.	Non-Pyrogenic
Hemolysis – Extract	The test article extract had a hemolytic index of -0.1%	Non-Hemoyltic

NTX-9004, iD3 Sensor/Ground Kit (4-ch) & NTX-9008, iD3 Sensor/Ground Kit (8-ch): Biocompatibility Testing was performed on the subject device; NTX-0400, Sensor Patch.

Test	Results	Conclusions
Cytotoxicity – Direct Contact method	The test article showed evidence of causing mild reactivity when exposed to L-929 cells directly. The test article met the requirements of the test and is considered to not elicit a cytotoxic effect. Risk Assessment has been performed which identified no indications of biological risk during intended clinical use.	Non-Cytotoxic
Sensitization – Buehler (closed patch)	The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig.	Non-sensitizer
Skin Irritation in Rabbits	There was no to well-defined erythema and no edema observed on the skin of the animals treated with the test article. The Primary Irritation Index for the test article was calculated to be 0.1. The response of the test article was categorized as negligible.	Non-Irritant

K. Summary of Performance Testing

Non-clinical testing was conducted in accordance with Design Controls and Risk Management to confirm

device performance for its intended use. The test results demonstrate that the device performs as well as the predicate device and/or conform to recognized consensus standards for the compared design inputs, including, but not limited to; operating conditions, electrical safety, electromagnetic compatibility, hardware and disposable device functionality, signal acquisition equivalence, biocompatibility, shelf-life, sterilization, packaging integrity and software validations. Additionally, a substantially equivalent comparative performance evaluation was performed using clinically relevant MMG signal simulation to capture a statistically significant sample for demonstration of high agreement with respect to performance of the predicate device.

Test	Test Method Summary	Results/Conclusions
Plug and Wire Disconnect Force Testing	Wire to plug connections (Probe-Probe Wire, Control Unit-Probe Wire, Control Unit-Ground Patch) must provide at least 2.2N of retention force (to withstand inadvertent disconnection) when pulled normal to plug). Instron Test at 300mm/min.	All samples passed the acceptance criteria. Design inputs satisfied. Substantially Equivalent.
Hydrogel Patch Adhesion Testing	Adhesive Sensor Patch and Ground Patches must provide at least 4N of retention force to HDPE (skin-approximating) test surface when pulled normal from surface by Sensor Wire or Ground Wire, respectively. Testing performed per PSTC 101 Type F.	All samples passed the acceptance criteria. Design inputs satisfied. Substantially Equivalent.
Sterility	Sterilization was validated per ISO 11137-1, ISO 11137-, and ISO 11137-32 using gamma irradiation at a sterility assurance level of 10^{-6}.	All samples passed the acceptance criteria. Design inputs satisfied. Substantially Equivalent.
Sterile Package Integrity	Sterile Packaging was validated per ISO 11607-1 and ISO 11607-2, including Seal Strength Testing per ASTM F88/F88M-21, Bubble-Leak Testing per ASTM F2096-19 (Reapproved 2019)	All samples passed the acceptance criteria. Design inputs satisfied. Substantially Equivalent.
Real Time Aging – Sterile	Sterile Packaging was maintained for 3 years of Real Time Aging and then subjected to Seal Strength Testing per ASTM F88/F88M-21, Bubble-Leak Testing per ASTM F2096-19 (Reapproved 2019)	All samples passed the acceptance criteria. Design inputs satisfied. Substantially Equivalent.
Accelerated Aging – Non-Sterile	Adhesive Sensor Patch and Ground Patches must provide at least 4N of retention force to HDPE (skin-approximating) test surface when pulled normal from surface by Sensor Wire or Ground Wire, respectively. Patches were subjected to 1 year of Accelerated Aging per ASTM F1980-21 and pull testing per PSTC 101 Type F.	All samples passed the acceptance criteria. Design inputs satisfied. Substantially Equivalent.
Environmental and Transport Stability	All devices were subjected, in packaging, to environmental preconditioning at stated transportation conditions per ASTM D4332 and then subjected to Transport Stability Testing per ASTM D4169 Cycle 13. Functional Testing of Devices performed afterwards per internal protocol. Sterile Packages subjected to Seal Strength Testing per ASTM F88/F88M-21,	All samples passed the acceptance criteria. Design inputs satisfied. Substantially Equivalent.

	Bubble-Leak Testing per ASTM F2096-19 (Reapproved 2019)	
EMC and Electrical Safety	System was tested for compliance to the requirements of IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, and IEC 60601-2-40. Additional Evaluation of EMC performance to IEC TR 60601-4-2 was completed	All samples passed the acceptance criteria. Design inputs satisfied. Substantially Equivalent.
Biocompatibility	Biocompatibility testing was conducted on the tissue contacting components of the system: The Hydrogel Patches were evaluated per requirements for intact skin contacting (≤24hr) devices: ISO 10993-1, ISO 10993-5, ISO 10993-10, and ISO 10993-23 (cytotoxicity, sensitization, irritation). The Stimulation Probe as evaluated per requirements for Externally communicating devices with tissue/bone and cerebrospinal fluid contact for limited duration (≤24hr). Testing was performed in accordance with 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-11, ISO 10993-23, and ISO 10993-4 (cytotoxicity, sensitization, intracutaneous irritation, acute systemic toxicity, material-mediated pyrogenicity, and indirect [extract] hemolysis).	All samples passed the acceptance criteria. Design inputs satisfied. Substantially Equivalent.
Sensor Characterization	The subject device measurements were compared to NIST traceable reference accelerometer at multiple frequencies to confirm performance was within specification with respect to low-pass filtering and % error.	All samples passed the acceptance criteria. Design Inputs satisfied. Substantially Equivalent.
Comparative Performance Evaluation	MMG-detection performance of subject device was compared to predicate device by subjecting both devices to MMG-positive and MMG-negative waveforms. Overall correlation was evaluated and confirmed to be >99% agreement.	All samples passed the acceptance criteria. Design Inputs satisfied. Substantially Equivalent.

L. Conclusion

The indications for use and intended use of the subject device are consistent with those of the predicate device. Comparison of technological characteristics and results of performance testing demonstrate substantial equivalence with the predicate device.