June 25, 2026

Neuralytix
Brian Dean
VP, Quality/Compliance
138 S Park Sq.
Suite 203
Fruita, Colorado 81521

Re: K260992
Trade/Device Name: iD3 Nav Decompression Probe (NTX-9005); iD3 Ball Tip Stim Probe (NTX-9006); iD3 Nav Ball Tip Probe (NTX-9007)
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: PDQ, ETN
Dated: March 25, 2026
Received: March 26, 2026

Dear Brian Dean:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260992

Please provide the device trade name(s).

iD3 Nav Decompression Probe (NTX-9005);
iD3 Ball Tip Stim Probe (NTX-9006);
iD3 Nav Ball Tip Probe (NTX-9007)

Please provide your Indications for Use below.

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 biologic
- 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

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(K) SUMMARY

A. Submitter Information

Manufacturer/Submitter:	Neuralytix, LLC 138 S Park Square, STE 203 Fruita, CO 81521
Contact Person:	Brian Dean (513) 240-2640 Dean@nerve.health

B. Date Prepared

March 16, 2026

C. Device Name

Trade/Proprietary Name:	iD3 Stimulation Probes (NTX-9005, NTX-9006, NTX-9007)
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 iD3 Stimulation Probes are substantially equivalent to the following primary predicate device:

- K243636 iD3 MMG System

E. Device Description

The Neuralytix iD3 Stimulation Probes are accessory devices to the Neuralytix iD3 MMG System, designed to allow surgeon-directed control of the system within the sterile field. The iD3 MMG 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 assists with nerve identification and assessment by alerting the surgeon when monitored nerves are activated. The device also assists 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 nerve health, or the conduction and neural transmission ability of a nerve, may change throughout surgery.

F. Technological Characteristics

Attribute	Subject Device NTX-9005	Subject Device NTX-9006	Subject Device NTX-9007	Primary Predicate: iD3 MMG System	Substantially Equivalent
Length	200 mm	225 mm	225 mm	200 mm	Yes
Stimulation Surface Area	14.5 mm^2	10.0 mm^2	10.0 mm^2	14.5 mm^2	Yes
Maximum Charge Density	13.79 uC/cm^2	20.00 uC/cm^2	20.00 uC/cm^2	13.79 uC/cm^2	Yes
Maximum RMS Current Density	3.9 mA/cm^2	5.6 mA/cm^2	5.6 mA/cm^2	3.9 mA/cm^2	Yes
Maximum Power Density	22.07 W/cm^2	32.00 W/cm^2	32.00 W/cm^2	22.07 W/cm^2	Yes
Electrical Insulation	Parylene C	Parylene C	Parylene C	Parylene C	Yes
Proximal Connector	USB-B	1.5mm touchproof	USB-B	1.5mm touchproof	Yes
Patient Contacting Material	316L Stainless Steel; Parylene C	316L Stainless Steel; Parylene C	316L Stainless Steel; Parylene C	316L Stainless Steel; Parylene C	Yes
Stimulation Control	Touch Screen via Control Unit or with buttons on handle	Touch Screen via Control Unit	Touch Screen via Control Unit or with buttons on handle	Touch Screen via Control Unit	Yes
Sterilization	Sterile via Ethylene Oxide; Single Use	Sterile via Gamma Radiation; Single Use	Sterile via Ethylene Oxide; Single Use	Sterile via Gamma 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.

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- 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 identical to the primary predicate device
Stimulation Probe	Substantially equivalent to predicate device in terms of conductive materials, dielectric properties, exposed stimulation surface areas and intended function.

I. Materials / Contact Classification

The contact classification for the patient-contacting components of all probes under this 510(k) submission (NTX-9005, Nav Decompression Stim Probe; NTX-9006, Ball Tip Stim Probe; and NTX-9007, Nav Ball Tip Probe) is externally communicating with tissue and 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.

J. 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 conforms 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	Plug-to-Connector connections (Probe Wire to Control Unit) must provide at least 2.2N of retention force to withstand inadvertent disconnection when pulled normal to plug.	Substantially Equivalent
Probe to Probe Handle Disconnect Force Testing	Probe-to-Handle connection must provide at least 2.2N of retention force to withstand inadvertent disconnection when pulled normal to plug.	Substantially Equivalent
Sterility	Sterilization for NTX-9005 and NTX-9007 were validated per ISO 11138-1:2017 and ISO 11138-2:2017 using Ethylene Oxide at a sterility assurance level of 10^{-6}. Sterilization for the NTX-9006 was validated per ISO 11137-1, ISO 11137-, and ISO 11137-32 using gamma irradiation at a sterility assurance level of 10^{-6}.	Substantially Equivalent
Sterile Package Integrity	Sterile Packaging was validated per ISO 11607-1 and ISO 11607-2, including Seal Strength Testing	Substantially Equivalent

	per ASTM F88/F88M-21, Bubble-Leak Testing per ASTM F2096-19 (Reapproved 2019)	
Accelerated Aging – Sterile	Sterile Packaging was maintained for an accelerated aging cycle representative of 1 year of Real Time and then subjected to Seal Strength Testing per ASTM F88/F88M-21, Bubble-Leak Testing per ASTM F2096-19 (Reapproved 2019)	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, Bubble-Leak Testing per ASTM F2096-19 (Reapproved 2019)	Substantially Equivalent
EMC and Electrical Safety	System was tested for compliance with the requirements of IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, and IEC 60601-2-40. Evaluation of EMC performance to IEC TR 60601-4-2 was completed	Substantially Equivalent
Biocompatibility	The Stimulation Probes were assessed as externally communicating devices with tissue/bone and cerebrospinal fluid contact for limited duration (<24hr) for endpoints of cytotoxicity, sensitization, intracutaneous irritation, acute systemic toxicity, material-mediated pyrogenicity, and indirect [extract] hemolysis.	Substantially Equivalent

K. Conclusion

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