July 22, 2026

Stroke DX
Richard Lilly
Consultant
300 Corporate Pointe
Suite 310
Culver City, California 90230

Re: K253840
Trade/Device Name: STEDI Scan Device
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II
Product Code: QAF
Dated: June 22, 2026
Received: June 22, 2026

Dear Richard Lilly:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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.	K253840

Please provide the device trade name(s).

STEDI Scan Device

Please provide your Indications for Use below.

The STEDI Scan Device is a bioimpedance spectroscopy device indicated to measure impedance ratios to aid in the assessment of cerebral fluid volume asymmetry between the cerebral hemispheres in adult patients undergoing neurological assessment

The STEDI Scan Device is an adjunct to standard methodologies for clinical evaluation

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.87 and 21 CFR § 807.92.

510 (k) number:K253840

I. SUBMITTER

Name:	NeuraNova Inc.
Address:	30 Corporate Pointe Unit 310 Culver City, CA 90230
Phone:	408-307-3759
Email:	rick@Neura-Nova.com
Contact Person:	Richard Lilly
Date Prepared:	19 JUN 2026

II. DEVICE INFORMATION

Name of Device:	STEDI Scan Device
Common or Usual Name:	N/A
Regulation Name:	Impedance Plethysmography
Regulation Number:	21CFR § 870.2770
Classification Panel:	Neurology
Regulatory Class:	Class II
Product Code:	QAF

III. PREDICATE DEVICE

Name	Manufacturer	510(k)#
Visor System	Cerebrotech Medical Systems	K182967

This Predicate has not been subject to a design-related recall. No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The STEDI Scan Device is a bioimpedance spectroscopy device used to monitor patients who are predisposed to cerebral fluid-volume changes. The Device utilizes sensor technology to non-invasively assess bioimpedance on the left and right sides of a patient's head by monitoring bioimpedance changes from biological tissue in response to an RF coil. The Device's software processes this signal data and provides a single value to the treating clinician that reflects the patient's cerebral fluid-volume status in the form of a Bioimpedance Asymmetry Score (BAS).

V. INDICATIONS FOR USE

The STEDI Scan Device is a bioimpedance spectroscopy device indicated to measure impedance ratios to aid in the assessment of cerebral fluid volume asymmetry between the cerebral hemispheres in adult patients undergoing neurological assessment.

The STEDI Scan Device is an adjunct to standard methodologies for clinical evaluation.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

A. INTENDED USE

	Predicate Visor System	Subject Device STEDI Scan Device	Comment
Indication for Use	The Visor System is a bioimpedance spectroscopy device indicated to measure impedance ratios to aid in the assessment of cerebral fluid volume asymmetry between the cerebral hemispheres in adult patients undergoing neurologic assessment.	The STEDI Scan Device is a bioimpedance spectroscopy device indicated to measure impedance ratios to aid in the assessment of cerebral fluid volume asymmetry between the cerebral hemispheres in adult patients undergoing neurological assessment.	Same as Predicate

	Predicate Visor System	Subject Device STEDI Scan Device	Comment
	The Visor System is an adjunct to standard methodologies for clinical evaluation.	The STEDI Scan Device is an adjunct to standard methodologies for clinical evaluation.	
21 CFR Section	21CFR § 870.2770	21CFR § 870.2770	Same as Predicate
Product Code	QAF	QAF	Same as Predicate
Target Population	Adult	Adult	Same as Predicate

B. TECHNOLOGICAL CHARACTERISTICS

Attribute	Predicate Visor System	Subject Device STEDI Scan	Comment
Monitoring Mode	Periodic. Baseline, then repeated as required	Periodic. Baseline, then repeated as required	Same as Predicate
Operating Principle	Multi-Frequency Bioimpedance Spectroscopy	Multi-Frequency Bioimpedance Spectroscopy	Same as Predicate
Software	Yes	Yes	Same as Predicate
Type of Energy	Low-Power Radio Frequency Current	Low-Power Radio Frequency Current	Same as Predicate
Frequency Range	30-310 MHz	0.5-30MHz	Modified See Note 1.
Displayed Parameter	Bioimpedance ratio	Bioimpedance ratio	Same as Predicate
Device Configuration	Non-invasive, antenna modules, and system controller	Non-invasive, RF coil-based sensor and system controller	Substantially Equivalent

Attribute	Predicate Visor System	Subject Device STEDI Scan	Comment
Physical Dimensions	Weight: 1.1 lbs Length: 9.0" Width: 9.0" Height: 2.8"	Weight: 18.6 lbs Length: 19.8" Width: 16.8" Height: 15.1"	Substantially Equivalent. Changes in size and weight do not raise new safety or efficacy concerns.
Power Source	Rechargeable Battery Removable Li-ion batteries	Mains powered with a medical-grade power supply	Substantially Equivalent Changes in the power delivered to the device do not raise new safety or effectiveness concerns.
Performance	Device detects and monitors bioimpedance ratios	Device detects and monitors bioimpedance ratios	Same as Predicate
Voltage	100 – 240	100 – 240	Same as Predicate
Frequency	50 – 60 Hz	50 – 60 Hz	Same as Predicate
Current	2.1 amp Power Adapter (for charging the Tablet) 1 amp for the Scanner Battery Charger	2.71 amp for Power Adapter 1.08 amp for Device	Substantially Equivalent Both systems use medical-grade power supplies to provide power to their components.

NOTE 1: Frequency Range: *The STEDI Scan Device operates at the same or lower frequency range than the predicate device. Lower frequencies generally carry less energy and are considered appropriate for use in biological tissue. Performance data indicate that this change does not adversely affect sensor performance. No new safety or effectiveness questions are raised by this difference.*

VII. PERFORMANCE DATA:

ELECTRICAL, THERMAL, AND MECHANICAL SAFETY AND ELECTROMAGNETIC COMPATIBILITY TESTING (EMC):

Electrical, thermal, mechanical safety, and EMC testing were conducted on the STEDI Scan Device, consisting of the STEDI Device, STEDI Controller, and a medical-grade power supply. The system complies with IEC 60601-1:2005 + AMD1:2012 + AMD2:2020, IEC 60601-1-2:2014 + AMD1:2020, and IEC TS 60601-4-2:2024.

SOFTWARE VERIFICATION AND VALIDATION TESTING:

Software verification and validation testing were conducted, and documentation was provided as recommended by the FDA guidance document, “Content of Premarket Submissions for Device Software Functions,” issued on June 14, 2023. The software documentation level for this Device was considered Basic because a failure or flaw of any device software function would not present a hazardous situation with a probable risk of death or serious injury.

SUMMARY OF PERFORMANCE TESTING:

Study	Description
Normative Human Bioimpedance Measurements	79 healthy adult volunteers established normative human bioimpedance and person-to-person variability.
Detection of bioimpedance asymmetry	A human head phantom with a septum dividing the right and left halves was used to measure bioimpedance asymmetry between the two hemispheres.
Mathematical model	A mathematical model validated the accuracy of the bioimpedance asymmetry readings.
Measurement Stability (Human)	Demonstrated day-to-day measurement stability in human subjects.
Conductivity Detection Test	Demonstrated the ability of the STEDI Device to detect different levels of electrical conductivity, and thus bioimpedance, in a test target with correlation to calibrated laboratory measurement tools.

CLINICAL TESTING:

Formal clinical performance testing was not required to support this medical Device, as the indication for use and technology are equivalent to those of the predicate device. A healthy volunteer study was conducted in a clinical setting using the STEDI Scan

Device to generate normative human bioimpedance measurements for the non-clinical performance testing section. The results from this study are presented below.

Results – all Scans

Parameter	Value
Subject	79
Trials	267
Mean ± Standard Deviation	1.025 ± 0.047
90% Confidence interval of the Mean	1.021 – 1.030
95% confidence interval of the Mean	1.020 – 1.031

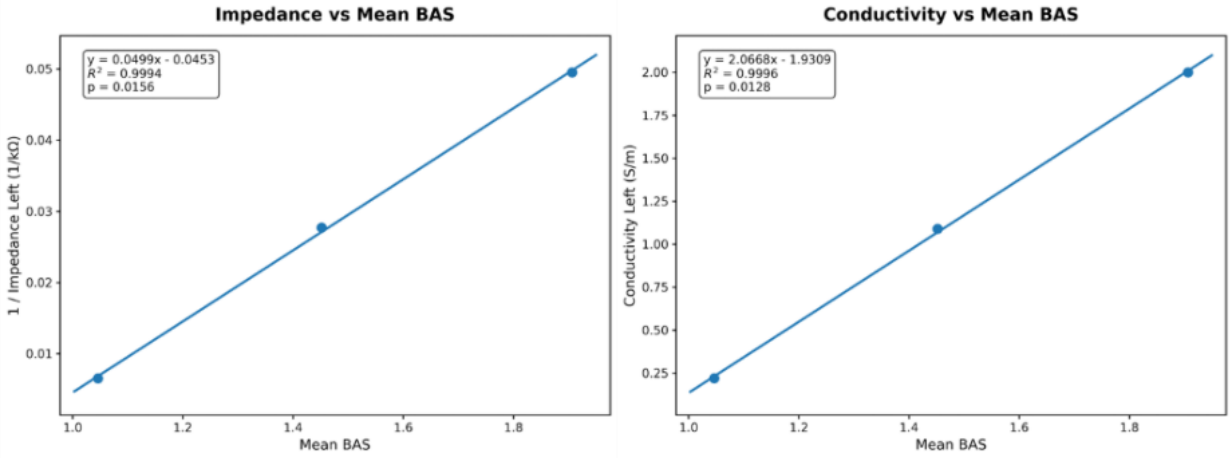
Results – First Scan Only

Parameter	Value
Subjects	79
Mean ± Standard Deviation	1.024 ± 0.045
90% Confidence interval of the Mean	1.016 – 1.033
95% confidence interval of the Mean	1.014 – 1.035

Bench Testing

To demonstrate that the STEDI System can detect and quantify bioimpedance asymmetry, a series of bench tests were performed on a head phantom. The head phantom is a plastic cylinder with a dome-shaped top and a diameter derived from the median dimensions of a human head. The phantom contains two separate chambers on the left and right sides and is mounted to the STEDI Device in place of the head cradle.

The chambers are filled with different mixtures of saline and tissue, representative of different amounts of fluid asymmetry in the brain. The right-side chamber remained sealed during the experiment, while the left-side chamber had varying ratios of saline to tissue. For each trial, the electrical conductivity and impedance of the variable mixture were measured, and the STEDI Device performed a scan and reported the BAS, as shown below.



BAS Score Measurement

The BAS was highly correlated with the measured conductivity and bioimpedance of the variable mixture. This demonstrates that the STEDI System can detect and quantify bioimpedance asymmetry.

VIII. CONCLUSIONS:

The NeuraNova STEDI Scan Device is substantially equivalent to the predicate device with respect to indications for use, technological characteristics, and performance. This 510(k) submission provides supporting details, data, and validation activities demonstrating that the differences between the subject device and the predicate device do not raise new questions of safety or effectiveness.