September 3, 2025

Forest Devices, Inc.
% David Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, NJ 07059 USA
1 (973) 232-0811

Re: K251726
Trade/Device Name: SignalNED System (RE Model)
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMC, OLT, GXY, OLU
Dated: July 5, 2025
Received: July 18, 2025

Dear David Yungvirt:

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)*
K251726

Device Name
SignalNED System (Model RE)

Indications for Use *(Describe)*
The SignalNED Device is intended to record and store EEG signals for the statistical evaluation of the human electroencephalogram (EEG) and display Quantitative EEG (qEEG) measures intended to help the user analyze the EEG. These measures include relative band power (e.g., alpha, beta, delta, theta) and band power asymmetry (displayed as a z-score compared to a normative database). The SignalNED does not provide any diagnostic conclusion about the patient's condition. The device is intended to be used on adults by qualified medical and clinical professionals.

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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K251726
510(k) Summary
510(k) Premarket Notification Summary of Safety and Effectiveness

This 510(k) summary was prepared on 7/14/2025 to provide an understanding of the basis for a determination of substantial equivalence in accordance with the requirements outlined in 21 CFR 807.92. The content of this document is also contained with the eSTAR format within Submitter's eSTAR application.

Submitter Information (Contact Details)

Applicant Name:	Forest Devices, Inc. Carmelo R. Montalvo
Applicant Address:	100 S Commons, Suite 102, PA 15212 United States
Applicant Contact:	*Telephone*: 412.522.0076
Applicant Contact:	*Email*: carmelo.montalvo@forestdevices.com

Date Prepared: July 18, 2025

Subject Device

K Number:	K251726
Device Trade Name:	SignalNED System (Model RE)
Common Name:	Electroencephalograph
Classification Name:	Reduced-Montage Standard Electroencephalograph
Regulation Number:	882.1400
Regulatory Class:	Class II
Primary Product Code:	OMC (Reduced-Montage Standard Electroencephalograph),
Other Product Codes:	OLT (Non-Normalizing Quantitative Electroencephalograph Software), GXY (Electrode, Cutaneous), and OLU (Normalizing Quantitative Electroencephalograph Software)

Primary Predicate Device

K Number:	K242306
Device Trade Name:	SignalNED System (Model RE)
Common Name:	Electroencephalograph
Classification Name:	Reduced-Montage Standard Electroencephalograph
Regulation Number:	882.1400
Regulatory Class:	Class II
Product Codes:	OMC (Reduced-Montage Standard Electroencephalograph), OLT (Non-Normalizing Quantitative Electroencephalograph Software), and GXY (Electrode, Cutaneous)

Secondary Predicate Device

K Number:	K171414
Device Trade Name:	BrainMaster Technologies, Inc. qEEG-Pro
Common Name:	Electroencephalograph
Classification Name:	Normalizing Quantitative Electroencephalograph Software
Regulation Number:	882.1400
Regulatory Class:	Class II
Product Codes:	OLU (Normalizing Quantitative Electroencephalograph Software)

Device Description Summary

The SignalNED Model RE machine uses 10 patient electrodes (4 left, 4 right, 2 midline), which are used to form the 8 channels. The SignalNED machine requires the use of the SignalNED Sensor Cap, and the system includes the following components:

- Portable EEG machine (Device)
- Battery & External Battery Charger
- SignalNED Sensor Cap
- SignalNED Sensor Cap Cable

The primary function of the SignalNED Model RE is to rapidly record EEG and derive Quantitative EEG (qEEG) measurements. These measurements include Relative Band Power for multiple bands (e.g., alpha, beta, delta, theta) at each electrode and band power asymmetry (displayed as a z-score compared to a normative database). These measurements are intended to help the user analyze the underlying EEG. The SignalNED Model RE (client) achieves its intended without relying on wireless connectivity. The SignalNED RE does not provide any diagnostic conclusion about the patient's condition.

Intended Use/Indications for Use

The SignalNED Device is intended to record and store EEG signals for the statistical evaluation of the human electroencephalogram (EEG) and display Quantitative EEG (qEEG) measures intended to help the user analyze the EEG. These measures include relative band power (e.g., alpha, beta, delta, theta) and band power asymmetry (displayed as a z-score compared to a normative database). The SignalNED does not provide any diagnostic conclusion about the patient's condition. The device is intended to be used on adults by qualified medical and clinical professionals.

Substantial Equivalence Comparison Summary

Primary Predicate K242306

Attribute	**Subject Device** The SignalNED Model RE System *K251726*	**Primary Predicate Device** The SignalNED Model RE System K242306	**Comparison**
Intended Use	To record and store EEG signals	To record and store EEG signals	Identical.
	Presents EEG signals in visual formats in device real-time	Presents EEG signals in visual formats in device real-time	Identical.
	Device does not have a diagnostic claim	Device does not have a diagnostic claim	Identical.
	Device does not provide any diagnostic conclusions about the patient's condition	Device does not provide any diagnostic conclusions about the patient's condition	Identical.
	Used on Adults	Used on Adults	Identical.
Technology	Records and stores EEG signals	Records and stores EEG signals	Identical.
	Uses specially designed cutaneous electrodes	Uses specially designed cutaneous electrodes	Identical.
	Uses analog to digital converter	Uses analog to digital converter	Identical.
	Uses frequency band of 0.5Hz – 100Hz	Uses frequency band of 0.5Hz – 100Hz	Identical.
	Device samples at 250Hz	Device samples at 250Hz	Identical.
	Displays calculated EEG measures	Displays calculated EEG measures	Identical.
	Use 2.4 GHz IEEE 802.11 b/g/n WIFI frequency	Use 2.4 GHz IEEE 802.11 b/g/n WIFI frequency	Identical.
	Uses Integrated Antenna	Uses Integrated Antenna	Identical.
	Features surface mount PCB module	Features surface mount PCB module	Identical.
	Battery powered	Battery powered	Identical.

Secondary Predicate K171414

Attribute	**Subject Device** The SignalNED Model RE System *K251726*	**Secondary Predicate Device** BrainMaster Technologies qEEG-Pro K171414	Comparison
Intended Use	To record and store EEG signals and to be used by qualified medical or qualified clinical professionals for the statistical evaluation of the human electroencephalogram	To be used by qualified medical or qualified clinical professionals for the statistical evaluation of the human electroencephalogram	Similar.
	Presents EEG signals in visual formats in device real-time	Presents EEG signals in visual formats in device real-time	Identical.
	Device does not have a diagnostic claim	Device does not have a diagnostic claim	Identical.
	Device does not provide any diagnostic conclusions about the patient's condition	Device does not provide any diagnostic conclusions about the patient's condition	Identical.
	Used on Adults	Used on Adults	Identical.
	Device does not provide a Diagnostic Conclusion or have a Diagnostic Claim	Device does not provide a Diagnostic Conclusion or have a Diagnostic Claim	Identical.
	Device does not provide automated alerts	Device does not provide automated alerts	Identical.
Technology	Displays calculated EEG measures (Power Spectrum Density)	Displays calculated EEG measures (Power Spectrum Density)	Identical.
	EEG data Comparison against normative database	EEG data Comparison against normative database	Identical.
	EEG Spectral Analysis on alpha, beta, delta, theta frequency bands	EEG Spectral Analysis on alpha, beta, delta, theta frequency bands	Identical.
	Provides qEEG measure of EEG Asymmetry	Provides qEEG measure of EEG Asymmetry	Identical.
	Displays Summary qEEG results	Displays Summary qEEG results	Identical.
	Provides post-hoc statistical evaluation of Human EEG	Provides post-hoc statistical evaluation of Human EEG	Identical.

Intended Use/Indications for Use Comparison

Primary Predicate: K242306 The Forest Devices SignalNED Model RE System

The SignalNED Model RE System (Subject Device) is identical to the Primary Predicate (Predicate K242306) in Intended Use. Both are intended to record and store EEG signals and present them in visual formats in real-time. Neither the Subject Device nor Predicate provides any diagnostic conclusion about the subject's condition or automated alerts of a clinical event. Additionally, neither device has a diagnostic claim, nor do they provide any diagnostic conclusions about the patient's condition. Both the Subject Device and the Predicate K242306 are intended to be used on adults by qualified medical and clinical professionals.

Secondary Predicate: K171414 BrainMaster Technologies, Inc. qEEG-Pro

The SignalNED Model RE System (Subject Device) is similar to the Secondary Predicate (Predicate K171414) in Intended Use. Both are intended to be used by qualified medical or qualified clinical professionals for the statistical evaluation of the human electroencephalogram. Neither the Subject Device nor Predicate provides any diagnostic conclusion about the subject's condition or automated alerts of a clinical event. Additionally, neither device has a diagnostic claim, nor do they provide any diagnostic conclusions about the patient's condition. Both the Subject Device and the Predicate K171414 are intended to be used on adults by qualified medical and clinical professionals.

Summary of Testing

Testing was required to verify and validate the software. The software change evaluated was for one additional qEEG feature as it relates to the predicates K242306 and K171414. Forest Devices used well established methods for conducting this testing. All testing passed. The predicate included non-clinical testing for Biocompatibility (ISO 10993), Electrical Safety (IEC 60601-1), Electromagnetic Compatibility (IEC 60601-1-2) and passed all Testing.

Test	Test Method Summary	Results
Shapiro-Wilk	The Shapiro-Wilk Test is a statistical test used to assess whether a sample dataset is normally distributed, with a null hypothesis that the sample comes from a normally distributed population. The z-score (Signal Score) normative database underwent normality verification to confirm the validity of z-score calculations and statistical analyses.	Passed. The asymmetry scores in the normative database conform to a normal distribution. Normality assumptions are valid for subsequent parametric analyses and z-score.
Regression Analysis	Linear regression analysis is used to predict the value of a variable based on the value of another variable, a regression analysis was performed to determine whether the z-score (Signal Score) depends on subject age.	Passed. The regression analysis revealed no statistically significant relationship between the subject's age and the absolute difference of band power between hemispheres ($p=0.1531$). Based on these findings, the Signal Score does not depend significantly on age, eliminating the need for age regression in the dataset.
Z-score Performance Bench Testing	The accuracy of the z-score measurement was verified using simulated data. A waveform was created by combining equal power sine waves with frequencies at the midpoint of desired frequency bands. As the simulated data is split evenly between hemispheres, the known characteristics of the data was verified posttest by the confirming the anticipated resultant z-score.	Passed. The Subject Device has demonstrated its proficiency in calculating the z-score repeatedly.

Technology Comparison

Attribute	**Subject Device** The SignalNED Model RE System *K251726*	**Primary Predicate Device** The SignalNED Model RE System K242306	**Secondary Predicate Device** BrainMaster Technologies qEEG-Pro K171414	Comparison
EEG Data Acquisition	10 electrodes to form 8 recording channels	10 electrodes to form 8 recording channels		Identical.
Data Acquisition Method	Analog to digital converter	Analog to digital converter		Identical.
Frequency band	0.5Hz – 100Hz	0.5Hz – 100Hz		Identical.
Sampling rate	250Hz	250Hz		Identical.
Displays calculated EEG measures	Yes	Yes		Identical. The Subject Device contains one additional qEEG feature. Other than this one software difference, the Subject and Predicate device are identical.
WIFI Frequency Standard	2.4 GHz IEEE 802.11 b/g/n	2.4 GHz IEEE 802.11 b/g/n		Identical.
Antenna Type	Integrated.	Integrated.		Identical.
Form Factor / Dimensions	Surface mount PCB module	Surface mount PCB module		Identical.
Integrated Processor and Memory	1.8GHz Quad Cortex™-A53 NXP i.MX 8M Plus	1.8GHz Quad Cortex™-A53 NXP i.MX 8M Plus		Identical.
Device Power	Battery Powered	Battery Powered		Identical.
Battery	100-240 V AC power adapter to battery charger	100-240 V AC power adapter to battery charger		Identical.
Differential input impedance	>2 Gohm	>2 Gohm		Identical.
Common mode input impedance	>1 Gohm	>1 Gohm		Identical.
Channel equivalent input noise	1.97 uVpp	1.97 uVpp		Identical.
Frequency band	0.5Hz – 30Hz	0.5Hz – 30Hz		Identical.
Low filter	0.5Hz	0.5Hz		Identical.
High filter	30Hz	30Hz		Identical.
Sampling rate	1kHz	1kHz		Identical.
WIFI Frequency Standard	2.4 GHz IEEE 802.11 b/g/n	2.4 GHz IEEE 802.11 b/g/n		Identical.
Antenna Type	Integrated	Integrated		Identical.
Displays calculated EEG measures	Yes	Yes	Yes	Identical.
Calculated EEG measures displayed	Power Spectrum Density		Power Spectrum Density	Identical.
EEG data Comparison against normative database	944 samples		2713 samples	Similar. Differences raise no additional questions of safety and efficacy.
EEG Spectral Analysis	Yes; 4 frequency bands (alpha, beta, delta, and theta)		Yes; 4 frequency bands (alpha, beta, delta, and theta)	Identical.
Provides qEEG measure of EEG Asymmetry	Yes.		Yes.	Identical.
Age Included in Normative Database	18 – 94 years		4 – 82 years	Similar. Differences raise no additional questions of safety and efficacy.
Displays Summary qEEG results	Yes.		Yes.	Identical.
Provides post-hoc statistical evaluation of Human EEG	Yes.		Yes.	Identical.

Conclusion

In conclusion, Forest Devices, Inc. has successfully demonstrated that the SignalNED is equivalent in safety and efficacy to the predicates devices (Primary Predicate Forest Devices SignalNED Model RE System, K242306; and Secondary Predicate BrainMaster Technologies, Inc. qEEG-Pro K171414) in the intended use, technological characteristics and safety and performance testing. Forest Devices, Inc. believes that we have successfully met or exceeded all conditions that are required for establishing substantial equivalence and obtaining FDA 510(k) clearance to market our medical device, the SignalNED Model RE System, for use with adult (18 and older) patients. The Forest Devices SignalNED Model RE System raises no additional questions of safety or effectiveness and is substantially equivalent to the cleared predicate devices K242306 and K171414. The differences in the Subject Device and predicates do not raise additional questions of safety or effectiveness. The device meets or exceeds all conditions that are required for establishing substantial equivalence and obtaining FDA clearance to market our medical device, the SignalNED Model RE System.