September 4, 2024

Forest Devices, Inc.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K242306
Trade/Device Name: SignalNED System (Model RE)
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMC, OLT, GWQ
Dated: August 5, 2024
Received: August 5, 2024

Dear Dave 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,

FDA 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K242306

Device Name
SignalNED System (Model RE)

Indications for Use *(Describe)*
The SignalNED Device is intended to record and store EEG signals and display Quantitative EEG (qEEG) (relative band power, e.g., alpha, beta, delta, theta), which is intended to help the user analyze the EEG. 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.

The SignalNED is intended to be used in a professional healthcare environment.

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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K242306

510(k) Summary

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

This 510(k) summary was prepared on 5/28/2024 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.
Applicant Address: 544 Miltenberger St 1st Floor, #4 Pittsburgh PA 15219 United States
Applicant Contact: *Telephone*: 412.522.0076
Applicant Contact: *Email*: carmelo.montalvo@forestdevices.com

Date Prepared: September 3, 2024

Device Name

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 Code(s)

Primary Product Code: OMC
Secondary Product Codes: OLT and GXY

Legally Marketed Predicate Devices

Predicate	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K170363	Ceribell Pocket EEG Device	OMC, Reduced-Montage Standard Electroencephalograph (Primary)
K143487	Lifelines iEEG 2.0	OLT, Non-Normalizing Quantitative Electroencephalograph Software (Secondary)
K171459	Ceribell Instant EEG Headband	GXY, Cutaneous Electrode (Secondary)

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 the Quantitative EEG (qEEG) measurement of Relative Band Power for multiple bands (e.g., alpha, beta, delta, theta) at each electrode. 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 and display Quantitative EEG (qEEG) (relative band power, e.g., alpha, beta, delta, theta), which is intended to help the user analyze the EEG. 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. The SignalNED is intended to be used in a professional healthcare environment.

Substantial Equivalence Comparison Summary

Attribute	**Subject Device** The SignalNED Model RE System *K Pending*	**Primary Predicate Device** Ceribell Pocket EEG K170363	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 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.

Intended Use/Indications for Use Comparison

Primary Predicate: K170363 Ceribell Pocket EEG

The SignalNED Model RE System (Subject Device) is identical to the Primary Predicate (Predicate) 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 Primary 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 Primary Predicate are intended to be used on adults by qualified medical and clinical professionals.

Technology Comparison

Device & Predicate Device(s):	K242306	K170363 OMC Predicate	K143487 OLT Predicate	K171459 GWQ Predicate	**Discussion**
General Device Characteristics					
EEG Data Acquisition	10 electrodes to form 8 recording channels	10 electrodes to form 8 recording channels			Similar
Data Acquisition Method	Analog to digital converter	Analog to digital converter			Similar
Frequency band	0.5 Hz – 100 Hz	0.5 Hz – 100 Hz			Similar
Sampling rate	250 Hz	250 Hz			Similar
Displays calculated EEG measures	Yes	Yes			Similar
WIFI Frequency Standard	2.4 GHz IEEE 802.11 b/g/n	2.4 GHz IEEE 802.11 b/g/n			Similar
Antenna Type	Integrated	Integrated			Similar
Form Factor / Dimensions	Surface mount PCB module	Surface mount PCB module			Similar
Integrated Processor and Memory	1.8GHz Quad Cortex™-A53	STM32 ARM Cortex-M3			Similar; The subject device

Device & Predicate Device(s):	K242306	K170363 OMC Predicate	K143487 OLT Predicate	K171459 GWQ Predicate	**Discussion**
	NXP i.MX 8M Plus	processor with 64 kB RAM			includes additional processing and memory capability
Device Power	Battery Powered	Battery Powered			Similar
Battery	100-240 V AC power adapter to battery charger	100-240 V AC power adapter to battery charger			Similar
Differential input impedance	>2 Gohm		>20 Mohm		Similar; electrical specification exceeds predicate device. This difference does not impact safety and effectiveness.
Common mode input impedance	>1 Gohm		>100 Mohm		Similar; electrical specification exceeds predicate device. This difference does not impact safety and effectiveness.
Channel equivalent input noise	1.97 µVpp		<3.5 µVpp		Similar; electrical specification exceeds predicate device. This difference does not impact safety and effectiveness.
Frequency band	0.5 Hz – 30 Hz		0.16 Hz – 70 Hz (-6 dB)		Similar; within range of predicate. This difference does not impact safety and effectiveness.
Low filter	0.5 Hz		0.5 Hz		Same
High filter	30 Hz		10 Hz – 100 Hz		Similar; within range of predicate. This difference does not impact safety and effectiveness.
Sampling rate	1 kHz		200,256 Hz		Similar; electrical

Device & Predicate Device(s):	K242306	K170363 OMC Predicate	K143487 OLT Predicate	K171459 GWQ Predicate	**Discussion**
					specification exceeds predicate device. This difference does not impact safety and effectiveness.
Displays calculated EEG measures	Yes		Yes		Same
Calculated EEG measures displayed	Power Spectrum Density		Spectrum, Power Spectrum, Density, band power, spectral edge, peak frequency		Similar; subject device is a subset to the predicate device.
WIFI Frequency Standard	2.4 GHz IEEE 802.11 b/g/n		2.4 GHz IEEE 802.11 b/g/n		Similar
Antenna Type	Integrated		Integrated		Similar
Where used	On the head			On the head	Similar
Means of Connection	A cable attached to the Sensor Cap to allow connection to SignalNED Model RE device			A cable attached to the headband to allow connection to an EEG acquisition/recording device	Similar
Electrode Type	Silver/silver-chloride (Ag/AgCl) electrodes			Silver/silver-chloride (Ag/AgCl) electrodes	Similar
Number of Electrodes	10 electrodes			10 electrodes	Similar
Electrode Form	Reservoir is filled with conductive electrolyte gel by separate dispensing container			Reservoir is filled with conductive electrolyte gel by separate dispensing container	Similar
Electrode Locations	The placement of the electrodes is according to the International 10-20 system of electrode placement or the American Electroencephalographic Society positioning system.			The placement of the electrodes is according to the International 10- 20 system of electrode placement or the American Electroencephalographic Society positioning system. The number of the electrodes in use is according to	Similar; both use the International 10-20 system of electrode placement or the American Electroencephalographic Society positioning system. The Subject device uses 10 electrodes

Device & Predicate Device(s):	K242306	K170363 OMC Predicate	K143487 OLT Predicate	K171459 GWQ Predicate	Discussion
				the needs of clinical practice.	whereas the Predicate device has configuration option from 9-19 electrodes.
Electrode Mounts	Thermoplastic Elastomer			Thermoplastic Elastomer	Same
Available Sizes	Various sizes (overall head size range 26 cm – 66 cm)			Various sizes (overall head size range 26 cm – 66 cm)	Same
Cap Material	Spandex blend: Nylon Knitted Fabric, 82% Nylon and 18% Spandex			Spandex blend: Nylon Knitted Fabric, 82% Nylon and 18% Spandex	Same
Type of Connector	Custom Touch-proof safety socket			Touch-proof safety socket DIN 42- 802	Similar; the electrical performance testing completed for both Subject and Predicate met the same requirements per FDA guidance. document "Cutaneous Electrodes for Recording Purposes- Performance Criteria for Safety and Performance Based Pathway," August 2020.

Intended Use/Indications for Use Comparison

Secondary Predicate: K143487 Lifelines iEEG 2.0

The Subject is identical to the Secondary Predicate (K143487, Lifelines iEEG 2.0) in Intended Use. Both ae intended to acquire, display, and store EEG signals, using cutaneous electrodes. Neither the Subject Device nor Secondary 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.

Technology Comparison

Secondary Predicate: K143487 Lifelines iEEG 2.0

Both the Subject Device and Secondary Predicate (K143487) are identical in that they display Quantitative Electroencephalograph (qEEG) measures that are derived from the acquired EEG. They are similar in differential input impedance, common mode input impedance, channel equivalent input noise, frequency band, low filter, high filter, sampling rate. The Subject exceeds the predicate in electrical specifications or is within the specified range of the Predicate.

Intended Use/Indications for Use Comparison

Secondary Predicates: K171459 Ceribell Instant EEG Headband

The Intended Use of the Subject Device and the Secondary Predicate (K171459, Ceribell Instant EEG Headband) is identical. Both use a disposable headpiece with an integrated array of 10 passive cutaneous electrodes that are applied to the patient's head to record EEG signals when connected to an EEG recording device.

Technology Comparison

Secondary Predicates: K171459 Ceribell Instant EEG Headband

The technology of the Subject Device and the Secondary Predicate (K171459, Ceribell Instant EEG Headband) is identical in type of patient contact, where used, means of connection, electrode type, number of electrodes and electrode form. The Subject and Secondary Predicate both follow placement of the electrodes is according to the International 10-20 system of electrode placement or the American Electroencephalographic Society positioning system. The Subject uses 10 electrodes, and the Secondar Predicate uses between 9-19 electrodes. The electrode mounts, sizes electrode cap materials, performance requirement, electrical connection compliance, designation for use are identical. Both are packaged non-sterile. Both demonstrate conformance to ISO 10993-1, ISO 10993-5, and ISO 10993-10.

Summary of Non-clinical Performance Testing

Testing	Objective and Outcome
Lead Off Detection	▪ Test is designed to validate the ability to detect disconnected electrodes. ▪ All testing passed acceptance criteria and details are contained in the test report.
Signal Acquisition Noise Levels	▪ Test is designed to assess noise levels in signal acquisition. ▪ All testing passed acceptance criteria and details are contained in the test report
Software ADC Conversion Accuracy	▪ Test is designed to verify accuracy of software in ADC conversion. ▪ All testing passed acceptance criteria and details are contained in the test report.
Quantitative Electroencephalogram (QEEG)	▪ Test is designed to ensure accuracy of the QEEG Relative Band Power calculation. ▪ All testing passed acceptance criteria and details are contained in the test report.
EC12:2020 Electrical Performance	▪ Test is designed to confirm compliance with EC12:2020 electrical standards. ▪ All testing passed acceptance criteria and details are contained in the test report.
Essential Performance Tests (IEC 80601-2-26)	▪ Test is designed to verify compliance with IEC 80601-2-26 essential performance requirements. ▪ All testing passed acceptance criteria and details are contained in the test report.

Electrical Performance

Electrical testing was conducted on the subject device. The subject device complies with IEC 60601-1, IEC 60601-1-2.
All testing passed.

Biocompatible Performance

The Forest SignalNED System is an EEG device used by trained medical professionals. The EEG machine does not touch the patient, but the Sensor Cap, which is part of the system, is placed on the patient's head (Limited Exposure less than 24 hours, Surface Contacting Medical Device that contacts intact skin surfaces). The SignalNED was assessed for biocompatibility under the requirements of ISO 10993 for the Biological Evaluation of Medical Devices for cytotoxicity, irritation, and sensitization within the Limited Contact duration (A), for Surface Medical Device for Intact Skin scope.

EN-ISO-10993-1:2020 the following test are the end points for our biocompatibility testing:

- ISO 10993-1: Risk Management
- ISO 10993-5: Cytotoxicity
- ISO 10993-10: Sensitization
- ISO 10993-23: Irritation or intracutaneous reactivity

All testing passed.

Conclusion

In conclusion, Forest Devices, Inc. has successfully demonstrated that the SignalNED is equivalent in safety and efficacy to the predicate in the intended use, technological characteristics and safety and performance testing. The Forest Devices SignalNED Model RE System raises no additional questions of safety or effectiveness and is substantially equivalent to the cleared predicate devices. 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.