September 4, 2024

EB Neuro S.p.A.
℅ Barry Ashar
President
Makromed, Inc.
88 Stiles Road
Salem, New Hampshire 03079

Re: K242305
Trade/Device Name: BE Plus PRO, Neurotravel LIGHT
Regulation Number: 21 CFR 882.1835
Regulation Name: Physiological Signal Amplifier
Regulatory Class: Class II
Product Code: GWL, GWQ, OLT, OLV
Dated: July 24, 2024
Received: August 5, 2024

Dear Barry Ashar:

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,

Jay R. Gupta -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242305

Device Name
BE Plus PRO
Neurotravel LIGHT

Indications for Use *(Describe)*
BE Plus PRO and Neurotravel LIGHT are intended to be used for Electroencephalography (EEG) and Polysomnography (PSG) exams, in combination with the Galileo NT Line software, for human beings to assist the user in diagnosis and monitoring of disorders of the central and peripheral nervous system and muscles.

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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510(k) #:

510(k) Summary

Prepared on: 2024-09-04

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	EB Neuro S.p.A.
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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	BE Plus PRO; Neurotravel LIGHT
Common Name	Physiological Signal Amplifier
Classification Name	Physiological Signal Amplifier
Regulation Number	882.1835
Product Code(s)	GWL, GWQ, OLT, OLV

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K121996	BE Plus LTM	GWL
K142064	Galileo NT Software	OLT

Device Description Summary

21 CFR 807.92(a)(4)

EEG Family devices (BE plus PRO and Neutratravel LIGHT) are active medical devices composed of various parts necessary to allow the achievement of their intended use. All these parts are intended to be interconnected to achieve the specified medical purpose.

EEG Family devices can be used in patient care institutions, diagnostics centers, neurosurgical hospitals and experimental laboratories of research institutions.

EEG Family devices are capable of acquiring the bioelectric signal generated by the electrical potentials of the neurons of the cerebral cortex, by means of suitable signal pickup electrodes. This signal, of the order of a few microvolts in amplitude, is first amplified and then filtered to clean it of noise and offset. It is then digitized by a high-resolution analog-to-digital converter at a certain sampling rate.

The signals acquired and converted into digital format are transferred to a Host PC through a special serial communication with a dedicated protocol and then can be processed by the Galileo NT software to complete the intended use.

The software part allows the implementation of many specific functions of visualization, measurement, processing and storage of brain signals, acquired by the acquisition unit, based on the clinical area of interest.

EEG Family devices are offered in the following two configurations:
- Mobile: All components are mounted on a mobile trolley.
- Portable: All components are mounted on a stationary desktop.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

BE Plus PRO and Neurotravel LIGHT are intended to be used for Electroencephalography (EEG) and Polysomnography (PSG) exams, in combination with the Galileo NT Line software, for human beings to assist the user in diagnosis and monitoring of disorders of the central and peripheral nervous system and muscles.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject devices are essentially a bundled package of the two predicate devices. As a result, their intended use is a combination of the intended uses of the predicate devices.

Technological Comparison

21 CFR 807.92(a)(6)

Introduction
The subject devices are essentially a bundled together package of our own previously cleared predicate devices. The first predicate device BE Plus LTM is an EEG amplifier hardware and the second predicate device Galileo NT is an EEG analysis software. They were previously 510(k) cleared on their own and are now being bundled together as a full montage EEG device.

Design
The subject devices essentially have the same design as the predicate devices. Both the subject and predicate devices use very similar components and accessories. The two subject devices are enhanced with obsoleting and replacing certain components of the predicate device with state-of-the-art components.

Operational Characteristics
The basic operational procedures including system setup, patient preparations, signal acquisition, data storage and analysis are identical between the subject and predicate devices.

Technological Characteristics
Subject devices' technological characteristics remain the same as those of the predicate devices.

Non-clinical Performance Characteristics
Due to the enhancements made to the electronic and electrical components, it was necessary to verify the electrical/mechanical/thermal safety and electromagnetic compatibility (EMC) of the subject devices. This was performed using the exact same test methods used for the predicate device using FDA-recognized external standards ANSI/AAMI ES60601-1, IEC 60601-1-2 and IEC 60601-2-26.

Conclusion
The subject devices do not introduce any new safety considerations in comparison to the predicate devices. All identified differences between the two systems are minor and without any known impact on safety or efficacy.

Item	Subject Devices		Predicate Devices		Comments
	BE Plus PRO	**Neurotravel LIGHT**	**BE Plus LTM (K121996)**	**Galileo NT (K142064)**	
Intended Use					
Intended Use	Medical Device intended to be used for Electroencephalography (EEG), and Polysomnography (PSG) exams, in combination with the Galileo NT Line software, for human beings to assist the user in diagnosis and monitoring of disorder of the central and peripheral nervous system and muscles.	Medical Device intended to be used for Electroencephalography (EEG), and Polysomnography (PSG) exams, in combination with the Galileo NT Line software, for human beings to assist the user in diagnosis and monitoring of disorder of the central and peripheral nervous system and muscles.	Acquisition of EEG, polygraphy and polysomnography signals and transmission of these to a PC during recording of neurophysiology examinations.	Intended to record and display EEG, Video-EEG, LTM, PSG, EMG, EP data acquired from the patient body through EB Neuro acquisition platform, to aid the diagnosis and monitoring of potential disorders of the central and peripheral nervous system and muscles.	Similar. See Note 1.
Intended Usage Site	Medical facilities with environment and electric network compatible with EEG usage standards.	Medical facilities with environment and electric network compatible with EEG usage standards.	Medical facilities with environment and electric network compatible with EEG usage standards.	The device is intended to be used in the clinical and hospital environment (including the hospital	Same

Item	Subject Devices		Predicate Devices		Comments
	BE Plus PRO	**Neurotravel LIGHT**	**BE Plus LTM (K121996)**	**Galileo NT (K142064)**	
				room, emergency room, intensive care unit, neuro-intensive care unit, critical care unit).	
Intended User	Neurology physicians, Neurophysiopathology technicians under physician's supervision, other physicians such as anesthesiologists, neonatologists and nursing staff of intensive care unit.	Neurology physicians, Neurophysiopathology technicians under physician's supervision, other physicians such as anesthesiologists, neonatologists and nursing staff of intensive care unit.	The "BE Plus LTM / GWi" amplifier system is intended to be used by or under direction of a physician for acquisition of EEG, polygraphy and polysomnography signals and transmission of these signals to a host PC during recording of neurophysiology examinations.	This device is intended to be used by qualified medical practitioners who will exercise professional judgment in using the information.	Same
Design - General					
System Configuration	It is a signal acquisition device connected to a PC with Galileo NT software running on the PC. It can be placed on a trolley	It is a signal acquisition device connected to a PC with Galileo NT software running on the PC. It can be placed on a trolley	It is a signal acquisition device intended to be connected to a PC with Galileo NT	It is a software only device, deployed on a Windows-based PC.	Similar. See Note 2.

Item	Subject Devices		Predicate Devices		Comments
	BE Plus PRO	**Neurotravel LIGHT**	**BE Plus LTM (K121996)**	**Galileo NT (K142064)**	
	(mobile version) or on a desk (portable version).	(mobile version) or on a desk (portable version).	software running on the PC. The PC can be placed on a trolley (mobile version) or on a desk (portable version).		
Power Supply	115 V medical power supply and internal battery.	115 V medical power supply.	115 V medical power supply and internal battery.	N/A	Same
PC Connection	USB, Ethernet, Wi-Fi.	USB	USB, Ethernet, Wi-Fi.	N/A	Same
Components and Accessories	Flash LED stimulator Pulse Oximeter module Windows PC Keyboard, mouse, printer Trolley Batteries Cables	Flash LED stimulator Pulse Oximeter module Windows PC Keyboard, mouse, printer Trolley Batteries Cables	Flash LED stimulator Pulse Oximeter module Batteries Cables	Software intended to be deployed on a PC equipped with keyboard, mouse, printer, and mounted on a desktop or trolley.	Similar. See Note 3.
Computer	- Desktop PC - Panel PC - Laptop PC	- Desktop PC - Panel PC - Laptop PC	Intended for: - Desktop PC - Panel PC - Laptop PC	Intended for: - Desktop PC - Panel PC - Laptop PC	Same
Operating System	Windows	Windows	Windows	Windows	Same
Software	Resident and runtime downloadable.	Resident and runtime downloadable.	Resident and runtime downloadable.	Resident and runtime downloadable.	Same

Item	Subject Devices		Predicate Devices		Comments
	BE Plus PRO	**Neurotravel LIGHT**	**BE Plus LTM (K121996)**	**Galileo NT (K142064)**	
Ports	2 DC Link 1 USB Link 2 DC Out/Aux I/O	1 USB Link 1 DC-AUX I/O	2 DC Link 2 DC Out/Aux I/O	N/A	Similar. See Note 4.
Signal Acquisition	Analog to digital acquisition at variable sampling rate	Analog to digital acquisition at variable sampling rate	Analog to digital acquisition at variable sampling rate	N/A	Same
Trigger Input (synchronization to external signal)	TTL LEVEL	TTL LEVEL	TTL LEVEL	N/A	Same
Trigger Output (synchronization for external signal)	Flash LED Stimulator is triggered by Galileo NT Line software running on host PC.	Flash LED Stimulator is triggered by Galileo NT Line software running on host PC.	Flash LED Stimulator is triggered by Galileo NT Line software running on host PC.	N/A	Same
Patient Circuitry Isolation	Patient isolation BF type	Patient isolation BF type	Patient isolation BF type	N/A	Same
Device Dimensions	120 (L) x 210 (W) x 48 (H) (mm)	120 (L) x 174 (W) x 31 (H) (mm)	170 (L) x 110 (W) x 45 (H) (mm)	N/A	Similar values
Device Weight	0.6 Kg	0.3 Kg	0.6 Kg	N/A	Similar values
Design - Acquisition					
Measurement Principle	The device provides acquisition of the physiological signal that is subsequently elaborated on the software on Host PC.	The device provides acquisition of the physiological signal that is subsequently elaborated on the software on Host PC.	The device provides acquisition of the physiological signal that is subsequently	N/A	Same

Item	Subject Devices		Predicate Devices		Comments
	BE Plus PRO	**Neurotravel LIGHT**	**BE Plus LTM (K121996)**	**Galileo NT (K142064)**	
			elaborated on the software on Host PC.		
Number of Channels	22-34 monopolar channels 4-12 bipolar channels 4 DC channels	32 monopolar channels 8 bipolar channels 5 GND – 3 NE	64 monopolar 4 DC channels	N/A	Similar. See Note 5.
CMRR	min>105 dB @ 16Hz (>100 dB @ 50Hz)	> 100 dB	> 100 dB	N/A	Similar values.
Noise	<0.15 µVrms @ 128 Hz (1.8 µVrms @ 32768 Hz)	<0.5µVrms	<0.3µVrms @ 256 Hz	N/A	Similar values. See Note 6.
Input Impedance	Differential : 20 MΩ	Differential : 6.6 MΩ	Differential : 6.6 MΩ	N/A	
Low Pass Filter	8KHz	512Hz	2KHz	N/A	Similar values. See Note 7.
High Pass Filter	DC	0.1Hz	Selectable 0.1-10Hz	N/A	
A/D Conversion	EEG channels: 24 bit ΣΔ ADC DC channels: 12 bit SAR ADC	EEG channels: 24 bit ΣΔ ADC	16 bit SAR effectively transferred to host	N/A	Similar technology with improvements in subject devices. See Note 8.
Sampling Rate	Max sample frequency 32768Hz/channe	Max sample frequency 32768Hz/channe	Max sample frequency 32768Hz/channe	N/A	All have more than adequate sampling rate for EEG/PSG measurements. See Note 9.

Item	Subject Devices		Predicate Devices		Comments
	BE Plus PRO	**Neurotravel LIGHT**	**BE Plus LTM (K121996)**	**Galileo NT (K142064)**	
Trigger Mode	Internal and External	Internal and External	Internal and External	N/A	Same
Ohmmeter	Measurement of the impedance in all bioelectric channels in the range 1-100 KOhm with precision of +/- 10%	Measurement of the impedance in all bioelectric channels in the range 1-100 KOhm with precision of +/- 10%	Measurement of the impedance in all bioelectric channels in the range 1-100 KOhm with precision of +/- 10%	N/A	Same
Performance Standards					
Electrical, Mechanical and Thermal Safety	ANSI AAMI 60601-1 IEC 60601-2-26	ANSI AAMI 60601-1	ANSI AAMI 60601-1	N/A	Same
Electromagnetic Compatibility	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	N/A	Same
Medical Device Software	IEC 62304	IEC 62304	IEC 62304	IEC 62304	Same
Medical Device Risk Management	ISO 14971	ISO 14971	ISO 14971	ISO 14971	Same

Note 1: The subject devices are essentially a bundled package of the two predicate devices. As a result, their intended use is a combination of the intended uses of the predicate devices.

Note 2: The subject devices are essentially a bundled package of the two predicate devices. As a result, their system configuration is a combination of the system configuration of the predicate devices.

Note 3: The subject devices are essentially a bundled package of the two predicate devices. As a result, their components and accessories are a combination of the components and accessories of the predicate devices.

Note 4: USB ports were not common on PCs when the predicate device BE Plus LTM was commercialized. USB ports are commonly used today and do not raise any additional questions of safety or effectiveness.

Note 5: Difference in the number and type of channels address different market needs and preferences, they do not raise any additional questions of safety or effectiveness.

Note 6: BE PLUS PRO offers better signal quality and lower noise with a more precise EEG measurement.

Note 7: Neurotravel LIGHT is limited to the EEG routine only, while BE PLUS PRO and BE PLUS LTM are set to a wider frequency band to also satisfy other applications (for example EP exams) for markets in countries other than the U.S.

Note 8: Sigma-Deltas (ΣΔ) have high resolution and are power efficient.

Note 9: Majority of brain wave activities fall below 512 Hz. The subject and predicate devices have sufficiently high sampling rates to capture these signals adequately. BE Plus PRO's exceptionally high sampling rate makes it more useful for advanced research studies.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-clinical Test Summary and Conclusion
Due to the enhancements made to the electronic and electrical components, it was necessary to verify the electrical/mechanical/thermal safety and electromagnetic compatibility (EMC) of the subject devices. This was performed using the exact same test methods used for the predicate device using FDA-recognized external standards ANSI/AAMI ES60601-1 and IEC 60601-1-2.

The subject devices passed all requirements of these standards. No deviations or exceptions were encountered.

Conclusion

The subject devices do not introduce any new safety considerations in comparison to the predicate devices. All identified differences between the two systems are minor and without any known impact on safety or efficacy.