DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 13, 2015

EB Neuro, SpA
c/o Allison Scott
Senior Regulatory Consultant
Navigant Consulting, Inc.
9001 Wesleyan Road, Suite 200
Indianapolis, IN 46268

Re: K142064
Trade/Device Name: Galileo NT
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Codes: OLT, GWF, GWQ, GWE, GWJ, IKN, OLV, JXE
Dated: February 9, 2015
Received: February 10, 2015

Dear Allison Scott:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

Device Name
Galileo NT

Indications for Use *(Describe)*
The GALILEO NT Line software is intended to record and display EEG, PSG, EMG and EP data acquired from the patient body through EBNeuro proprietary, FDA cleared, Acquisition Platform.(BE Plus LTM K121986, BE micro K093728, Nemus 2 system K133517.)

The device is intended to be used in the clinical and hospital environment (including the hospital room, emergency room, intensive care unit, neuro-intensive care unit, critical care unit) to aid the diagnosis and monitoring of potential 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Traditional 510(k) Summary

807.92(a)(1)

Submitter Information

EB Neuro, S.p.A.
Via Pietro Fanfani 97/a
Florence, Italy 50127

Contact Person: Allison Scott
317.228.8719
Allison.Scott@Navigant.com

Date: February 12, 2015

807.92(a)(2)

Devices

Common Name: Electroencephalograph Software

Trade Name: Galileo NT Line

Classification Name(s): Electroencephalograph; Evoked Potential; Electromyograph; Polisomnograph; Nerve Conduction Velocity Measurement

Classification Number: 21 CFR 882.1400 (Product Code: OLT); 21 CFR 882.1870 (Product Code: GWF); 21 CFR 882.1400 (Product Code: GWQ); 21 CFR 882.1890 (Product Code: GWE); 21 CFR 882.1900 (Product Code: GWJ); 21 CFR 882.1375 (Product Code: IKN); 21 CFR 882.1940 (Product Code: OLV); 21 CFR 882.1550 (Product Code: JXE)

Regulatory Class: Class II

807.92(a)(3)

Predicate Device(s)

Device	Owner	510(k)
BRAVO Multimodality System	Nicolet Biomedical, Inc	K991054
Nemus 1 System	EBNeuro SpA	K073415
Twin Plus Software	Astromed-Med, Inc.	K012976

807.92(a)(4)

Device Description

Galileo NT Line is a software package running on a Personal Computer under Windows Operative System. This package is devoted to the complete management of various exams in the Neurodiagnostic field of application, as electroencephalography, electromyography, Evoked Potentials etc.

The product is essentially a suite of applications dedicated to the comprehensive management of neurological diagnostics in a Department of Neurology, Neurophysiology, etc. .., starting from the patient's acceptance, the execution of specific tests, and finally to the production of the exam reports. The package is substantially made by a common "platform" and by various independent modules, each of which is devoted to a particular application (EEG, Video EEG, EMG, EP, ICU, etc.). All the parts of the package together with the related User Documentation are residing on the same distribution media (a DVD).

As illustrated by figure 1 below, GALILEO NT Line (simply Galileo NT in other documents of this submission) is a "*software only device*" that can control and acquire data from a series of (FDA cleared) Amplifier platforms developed by EBNeuro for the Neurodiagnostic field and specifically :

1. BE micro (K093728)
2. BE Plus LTM (K121986)
3. Nemus 2 (K133517)

For each of the above devices, Galileo NT provides the appropriate "software interface" module in order to allow the control of the Amplifier (and of all the accessories eventually provided with it, as, for example, the Evoked Potential stimulators embedded in the Nemus 1 and 2 hardware) and in order to collect the acquired data. The data, once acquired from the amplifier, are "passed" to the specialized module for successive handling as display, measure, printing, trending, archiving and so on.

807.92(a)(5)

Intended Use

The GALILEO NT Line software is intended to record and display EEG, PSG, EMG and EP data acquired from the patient body through EBNeuro proprietary, FDA cleared, Acquisition Platform.(BE Plus LTM K121986, BE micro K093728, Nemus 2 system K133517.)

The device is intended to be used in the clinical and hospital environment (including the hospital room, emergency room, intensive care unit, neuro-intensive care unit, critical care unit) to aid the diagnosis and monitoring of potential disorders of the central and peripheral nervous system and muscles

807.92(a)(6)

Technological Characteristics

Both the Bravo Multimodality System and the Nemus 1 System are devices that include both a “software device” and a “hardware device” (the Amplifier/Stimulators). In this context comparison will be made among the Galileo NT Line software and the software part of the predicate devices

The “software device” of the Nemus 1 is simply “a part” of the whole Galileo NT Line package. The Nemus 1 software is actually made by the Galileo NT PMS module (the “main” module) and the Galileo NT Line EMG/EP module. This two modules, described in detail in the other parts of this submission, where already evaluated together the other parts of Nemus 1 system (hardware + software) with K073415.

The substantial difference between the two devices is that while Nemus System software is capable to handle only EMG and EP data, the Galileo NT Line package is capable to handle EMG, EP, and EEG and VIDEO EEG data as detailed in other part of this submission. In other words the Galileo NT Line package includes, in addition to the PMS and EMG/EP modules, the EEG and ICU modules.

The two products are similar in their “multimodal” concept: a common platform that using specialized hardware(s) is capable to acquire, display and record data of different clinical application (EEG, EMG, EP) so acting as an electroencephalograph, an electromyography or an evoked potential device.

Both devices include a patient database on which store patients data and exams reports.

A substantial difference between the two devices is that the Bravo System can handle also TCD data other than EEG/EMG/EP data, while Galileo NT Line does not handle TCD data.

The Twin Plus Software and Galileo NT are indicated for EEG and PSG. Both packages use the output of an appropriate capture hardware on the PC to digitize and store patient image data. Provision is included to playback video data synchronized with the EEG waveform display. This technique is referred as VIDEO-EEG. Both devices perform real time collection, real time display, data collection and recording to disk of real time video and audio data, usually an image of the patient being monitored. Both device performs review and analysis of previously recorded data including the ability to look back the old data while real time recording of ongoing data is in progress. Both devices work with a number of different amplifier system with various digital interface models (EBNeuro BE Plus LTM, BE micro, Nemus 2 for Galileo NT, Grass Telefactor BEEHIVE, BEEHIVE USB, TS for Twin Plus) Each of these hardware device have their own separate 510(k) marketing authority. Both device allow specific section of data to be easily selected for further analysis including frequency and amplitude measurement, potential mapping, spectral analysis, and frequency band mapping. Both device handle a patient/recording data base.

A substantial difference between the devices is that the Twin Plus software has a Seizure Analysis module and performs a semiautomatic sleep data scoring, where the Galileo NT does not have this module or scoring. Galileo NT allows EP and EMG recording, Twin Plus does not handle EP or EMG data recording.

807.92(b)(1)

Summary of Non-Clinical Tests

The Galileo NT has been designed and developed according to the following medical device industry standards.

- ISO 14971 Second Edition 2007
- IEC 62304 First Edition 2006
- IEC 62366 Edition 1.0 2007

807.92(b)(2)

Summary of Clinical Tests

No clinical tests were performed.

807.92(b)(3)

Conclusion

The Galileo NT Line is substantially equivalent to the legally marketed devices and conforms to applicable medical device safety and performance standards.