June 27, 2026

Time is Brain, S.L.
Carlos Navarro
RAQA Manager
Carretera de Canyet s/n
Badalona, Barcelona 08916
Spain

Re: K253301
Trade/Device Name: BraiN20® (BraiN20)
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator
Regulatory Class: Class II
Product Code: GFW, GXY, IKN
Dated: January 22, 2026
Received: May 26, 2026

Dear Carlos Navarro:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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

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)*
K253301

Device Name
BraiN20® (BraiN20)

Indications for Use *(Describe)*
The BraiN20® is intended for use in monitoring neurological status by recording the N20 response of somatosensory evoked potentials (SEP).

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.

SUBMITTER

Manufacturer: Time is Brain S.L.

Address: Carretera del Canyet s/n, 08916 Badalona, Barcelona, Spain

Contact Person: Carlos Navarro Sobrino

Telephone Number: (+34) 609 199 384

Email: cnavarro@tibtimeisbrain.com

Trade Name: BraiN20®

Date Prepared: 26/June/2026

DEVICE

Device Name: BraiN20®

Common Name: Evoked Response Electrical Stimulator / Somatosensory Evoked Potential Monitoring System

Classification Name: Evoked Response Electrical Stimulator

Regulation Number: 21 CFR 882.1870

Product Code: GWF

Device Class: Class II

PREDICATE DEVICES

Primary Predicate Device:

- EPAD Device (K132616)

Secondary Predicate Device:

- NeuroEPG System (K123843)

ITEM	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	ADDITIONAL PREDICATE DEVICE	EQUIVALENCE
	BraiN20®	**EPAD (Evoked Potential Assessing Device) (K132616)**	**NeuroEPG System (K123843)**	
Regulation	21 CFR 882.1870	21 CFR 882.1870	21 CFR 882.1870	Equivalent
Product Code	GWF, GXY, IKN	GWF, GXY, IKN	GWF, GWJ, GXY	Equivalent

ITEM	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	ADDITIONAL PREDICATE DEVICE	EQUIVALENCE
	BraiN20®	**EPAD (Evoked Potential Assessing Device) (K132616)**	**NeuroEPG System (K123843)**	
Indications for Use	The BraiN20® is intended for use in monitoring neurological status by recording the N20 response of somatosensory evoked potentials (SSEP).	The EPAD is intended for use in monitoring neurological status by recording somatosensory evoked potentials (SSEP) or assessing the neuromuscular junction (NMJ).	The NeuroEPG System is an evoked response testing and diagnostic device that is capable of eliciting, acquiring and measuring auditory and somatosensory evoked potentials. The intended use of the NeuroEPG System is to objectively record evoked responses from patients 18 years of age and older, upon the presentation of sensory stimuli. The product is indicated for use as a diagnostic agent adjunctive tool and sensory related disorders (i.e., auditory, somatosensory) and in surgical procedures for intraoperative monitoring. The NeuroEPG system was intended to be used by trained personnel in a hospital, clinic, EEG/EP technologists, surgeons, or physician's office, operating room, or other appropriate setting. The anatomical sites of contact for auditory evoked potential testing are the patients ear canal (with the contact object being a sound delivery earbud and the patient's head) and possibly other body sites (with the contact object being electrodes that are capable of measuring bio potentials). The anatomical sites of contact for somatosensory evoked potential testing are the patients upper slash lower limbs (with the contact object being skin surface electrodes) and the patient's head and possibly other body sites (with the contact object being electrodes that are capable of measuring bio potentials).	Substantially Equivalent
Device Description	BraiN20® is an active, portable, and non-invasive medical device with a rechargeable battery,	The EPAD Headbox contains a complete data acquisition system that has built-in amplifiers,	The NeuroEPG system is an evoked response testing and diagnostic device that is capable of eliciting,	BraiN20® operates without wireless communication.

ITEM	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	ADDITIONAL PREDICATE DEVICE	EQUIVALENCE
	BraiN20®	**EPAD (Evoked Potential Assessing Device) (K132616)**	**NeuroEPG System (K123843)**	
	integrated touchscreen, embedded software, where patient skin contact occurs exclusively through disposable accessory electrodes (stimulation and recording) applied to the skin surface for transient use (<24 h) for SEP somatosensory evoked potential) monitoring. The objective of the BraiN20® is to generate and identify the presence or absence of the N20 SEP component generated (and in case of detection, its amplitude and latency), so that through the processing of the registration data information can be offered that will be presented on the screen to the MD user. The BraiN20® medical device is a portable MD capable of stimulating and recording at the same time and in a synchronized manner to process the data and robustly analyze the N20 SEP component. BraiN20® consists of the main device, CMAP stimulation and recording, cables for CMAP stimulation and recording electrodes and acquisition (or recording) electrodes with its textile support holding. The BraiN20® medical device allows you to generate electrical pulses, carry out the acquisition, configure and control the analysis of the recorded signal and display the results on the screen. It is mainly composed of the stimulation module and the acquisition module, which are physically	analog to digital converters, and digital signal processors. User interface is via tablet touchscreen computer provided with the EPAD System and running the Android operating system. The EPAD software application is preloaded onto the tablet. Data can be transferred to an external computer for archiving purposes. Communication between the EPAD Headbox and tablet is via Bluetooth wireless or USB connection. Electrode cables are provided for left and right stimulation and left and right acquisition, color coded for correct connection to the EPAD Headbox: Custom cutaneous electrodes for stimulus and acquisition are provided by SafeOp for use with the EPAD. A total of 11 electrodes are applied for full patient monitoring (upper and lower limbs). The SafeOp electrodes are wet gel, single patient use, disposable, and biocompatible for short term (<24 hours) use on intact skin.	acquiring, and measuring auditory and somatosensory evoked potentials. The NeuroEPG System is intended to objectively record evoked response from patients 18 years of age and older, upon presentation of sensory stimuli. The product is indicated for use as a diagnostic aid and adjunctive tool in sensory related disorders (i.e., auditory, somatosensory) and in surgical procedures for intraoperative monitoring.	Substantially Equivalent

ITEM	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	ADDITIONAL PREDICATE DEVICE	EQUIVALENCE
	BraiN20®	**EPAD (Evoked Potential Assessing Device) (K132616)**	**NeuroEPG System (K123843)**	
	isolated and also have independent battery power systems. The BraiN20® medical device has a dual-core processor in the acquisition module that allows one of them to be dedicated to acquisition management, interface, storage, communication with the acquisition module and external systems, and the other core exclusively for the processing and detection algorithm of the N20 SEP. In the stimulation module there is a second processor dedicated to stimulation control. BraiN20® medical device analyses EEG and EMG data in real time on the device itself. In addition, it has an SD card for data storage. For the acquisition of EEG and EMG, the BraiN20® has standardized DIN 1.5mm type connectors and for stimulation it has the MINI-MED connector suitable for clinical applications (to which the specific cable for the type of electrode must be connected). Finally, the BraiN20® medical device has an embedded touch screen that allows you to configure and launch both stimulation and acquisition and subsequently display the N20 SEP amplitude and latency information, and a graph of the N20 SEP measured.			
Modalities	SSEP	SSEP NMJ	SSEP AEP	Substantially Equivalent BraiN20® mode SSEP is a subset
Operating	The device operates with a	Google Android	Microsoft Windows (2000 or	The subject

ITEM	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	ADDITIONAL PREDICATE DEVICE	EQUIVALENCE
	BraiN20®	EPAD (Evoked Potential Assessing Device) (K132616)	NeuroEPG System (K123843)	
System	proprietary embedded operating system		XP)	device operates with a proprietary embedded operating system, whereas the predicate devices use commercial operating systems such as Google Android or Microsoft Windows Substantially Equivalent
Interface Connection	Not connected	Bluetooth or USB	USB	BraiN20® is not connected
User Interface	Portable Touchscreen	Tablet Touchscreen	Not stated	BraiN20® integrates display. Substantially Equivalent to Primary Predicate
Operating Environment	Temperature: 20 – 28 °C. Relative humidity: 30 – 60 % RH. Pressure: 860 – 1060 hPa.	Temperature: 10° - 40°C Relative Humidity: 30-75%	Not stated	Substantially Equivalent to Primary Predicate
Waveform Acquisition				
Number of Amplifier Channels	4	8	Not stated	Substantially Equivalent to Primary Predicate
Waveform Display	Yes	Yes	Yes	Equivalent
Stimulation				
Number of Stimulation Channels	2	6	Not stated	Substantially Equivalent to Primary Predicate
Stimulator Type	Current controlled	Current controlled	Current controlled	Equivalent
Maximum Stimulation Intensity	45 mA	100 mA	25 mA	Substantially Equivalent to Primary Predicate
Stimulation Frequency	1-10 Hz	0.1-50 Hz	0.1-100 Hz	Substantially Equivalent
Maximum Voltage	180 V with 10 kΩ load impedance	380 VDC with a 3.8 kΩ load impedance	Not stated	Substantially Equivalent to Primary

ITEM	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	ADDITIONAL PREDICATE DEVICE	EQUIVALENCE
	BraiN20®	EPAD (Evoked Potential Assessing Device) (K132616)	NeuroEPG System (K123843)	
				Predicate
Pulse Width	100-500 us	100-300 us	10-1000 usec	Substantially Equivalent to Primary Predicate
Waveform	Monophasic	Monophasic	Monophasic or Biphasic	Equivalent to Primary Predicate
Low Frequency Filter	30 Hz	0.1 – 500 Hz	Not stated	Substantially Equivalent to Primary Predicate
High frequency filter	230 Hz	30 – 3000 Hz	Not stated	Substantially Equivalent to Primary Predicate
Electrodes				
Anatomical Sites	SSEP: Upper limbs and head	SSEP: Upper/lower limbs and head/neck	SSEP: Upper/lower limbs and head/neck AEP: Head	Equivalent
Type	Custom cutaneous electrodes for use with BraiN20® only	Custom cutaneous electrodes for use with EPAD only	Custom cutaneous electrodes for use with NeuroEPG only	Substantially Equivalent
Conductive Gel	Wet gel	Wet gel	Not stated	Equivalent to Primary Predicate
EEG Connectors	1.5mm DIN connector	Nicomatic three pin	Not stated	Standardized connector Substantially Equivalent to Primary Predicate
Current Density	Not stated	<0.75 mA_{rms}/cm^2	Not stated	Recording electrodes are standard and approved by FDA. Stimulation electrodes are a well stablished technology.
Sterility	Non-sterile, single patient use, disposable	Non-sterile, single patient use, disposable	Non-sterile, single patient use, disposable	Equivalent

Conclusions Regarding Substantial Equivalence

Based on a comprehensive comparison with the primary and secondary predicate devices (EPAD Device, K132616, and NeuroEPG System, K123843), the BraiN20® device is substantially equivalent in terms of intended use, fundamental technology, and overall safety and effectiveness.

While BraiN20® includes certain design differences—such as a limited testing mode (SSEP only), absence of wireless communication, a proprietary embedded operating system, integrated display, and multiple safety and usability enhancements. These differences do not raise new questions of safety or effectiveness.

Performance testing demonstrated compliance with the standards identified in this submission.

DEVICE DESCRIPTION

BraiN20® is an active, portable, non-invasive medical device intended for monitoring neurological status through the acquisition and analysis of somatosensory evoked potentials (SSEP), specifically the N20 cortical response.

The system consists of a central unit incorporating embedded software, rechargeable batteries, stimulation and signal acquisition electronics, and an integrated touchscreen display. Patient contact is achieved through disposable stimulation and recording electrodes applied to intact skin for transient use (<24 hours).

BraiN20® delivers controlled electrical stimulation and acquires electrophysiological signals in a synchronized manner. Embedded software analyzes the recorded signals in real time to identify the presence or absence of the N20 response and, when detected, determine its latency and amplitude. Results are displayed directly on the device.

INTENDED USE

The BraiN20® is intended for use in monitoring neurological status by recording the N20 response of somatosensory evoked potentials (SSEP).

The device provides objective electrophysiological information and is not intended to provide a diagnosis independently of clinical assessment.

PERFORMANCE TESTING

Performance testing was conducted to demonstrate that BraiN20® performs as intended and is substantially equivalent to the predicate devices.

Electrical Safety

Electrical safety testing was performed in accordance with applicable requirements of:

- IEC 60601-1
- IEC 60601-2-10
- IEC 60601-2-40

Electromagnetic Compatibility

Electromagnetic compatibility (EMC) testing was conducted in accordance with:

- IEC 60601-1-2

Software Verification and validation

Software verification and validation activities were performed in accordance with:

- IEC 62304

Biocompatibility

Patient-contacting materials were evaluated for biocompatibility in accordance with:

- ISO 10993-1
- ISO10993-5
- ISO 10993-10

Bench Performance Testing

Bench testing was performed to evaluate system functionality, signal acquisition performance, stimulation performance, battery operation, reliability, hardware integration, and overall system operation. (IEC 62133-2 for battery operation).

Shelf Life Testing

Shelf-life testing, including accelerated aging evaluations, was conducted to support a 24-month shelf-life for applicable device components.

Additional testing demonstrated that the device maintains performance throughout its intended service life when maintained according to manufacturer recommendations.

Usability Evaluation

Usability testing was conducted in accordance with applicable human factors and usability engineering principles, including IEC 62366-1 and IEC 60601-1-6

Clinical Testing

No clinical studies were required or relied upon to support a determination of substantial equivalence for this submission.

CONCLUSION

The information provided in this submission demonstrates that BraiN20® has the same intended use and similar technological characteristics as the identified predicate devices.

Performance testing confirmed that the device meets applicable safety, electromagnetic compatibility, software, biocompatibility, usability, shelf-life, and functional performance requirements.

Any differences between BraiN20® and the predicate devices do not raise new questions of safety or effectiveness. Therefore, BraiN20® is substantially equivalent to the legally marketed predicate devices identified in this submission.