June 13, 2026

Neuroelectrics Barcelona S.L.U.
Ana Maiques
CEO
Av. Tibidabo, 47 Bis
Barcelona, 08035
Spain

Re: K261604
Trade/Device Name: Enobio Dx (Enobio Dx 8);Enobio Dx (Enobio Dx 20);Enobio Dx (Enobio Dx 32)
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ, GWL, GXY
Dated: May 14, 2026
Received: May 14, 2026

Dear Ana Maiques:

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261604

Device Name
Enobio Dx (Enobio Dx 8);
Enobio Dx (Enobio Dx 20);
Enobio Dx (Enobio Dx 32);

Indications for Use *(Describe)*
Enobio Dx is a wireless, battery-operated, and portable electrophysiology sensor system for the recording of electroencephalograms (EEG). Enobio Dx is available in three different models capable of providing either 8, 20, or 32 channels respectively. Enobio are portable EEG monitoring devices of 8, 20, and 32 channels intended for use in clinical patient monitoring for use in hospitals and other medical environments. The Enobio is intended to acquire, store, transmit and display electrophysiological signals as an aid in diagnostics. The system digitizes analogue EEG signals collected by a cap with electrodes and uses WiFi connectivity to transmit the EEG data to a dedicated host computer with the software. This device is intended to be used by trained health-care personnel. It is restricted to sale by or on order of a physician.

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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Preparation date: June 10, 2026

Special 510(k) Summary

K261604

Enobio Dx

Contact Details (21 CFR 807.92(a)(1))

- Applicant Name: Neuroelectrics Barcelona S.L.U.
- Applicant Address: Av. Tibidabo, 47 bis Barcelona 08035 Spain
- Applicant Contact Telephone: +0034932540366
- Applicant Contact: Ms. Ana Maiques
- Applicant Contact Email: qa@neuroelectrics.com

Device Name (21 CFR 807.92(a)(2))

- Device Trade Name:
  - Enobio Dx (Enobio Dx 8);
  - Enobio Dx (Enobio Dx 20);
  - Enobio Dx (Enobio Dx 32);
- Common Name: Electroencephalograph (EEG)
- Classification Name: Electroencephalograph
- Regulation Number: 21 CFR 882.1400
- Product Code(s): GWQ (primary), GWL, GXY

Legally Marketed Predicate Devices 21 CFR 807.92(a)(3)

- Predicate #: K162681
- Predicate Trade Name (Primary Predicate is listed first): Enobio Wireless EEG
- Product Code: GWQ Full-Montage Electroencephalograph

Device Description Summary (21 CFR 807.92(a)(4))

The Enobio Dx system is a portable, wireless, battery-operated electroencephalography (EEG) system intended for clinical patient monitoring in hospitals and other medical environments. The system is designed to acquire, digitize, store, transmit, and display electrophysiological signals from the human scalp using non-invasive electrodes, as an aid in diagnosis.

The system is available in multiple configurations providing 8, 20, or 32 EEG channels and is intended to be used by trained healthcare professionals. The Enobio Dx system operates in conjunction with dedicated host software, NIC-EnobioDx, which provides configuration, control, visualization, and data management functionality.

Intended Use/Indications for Use (21 CFR 807.92(a)(5))

Enobio Dx is a wireless, battery-operated, and portable electrophysiology sensor system for the recording of electroencephalograms (EEG). Enobio Dx is available in three different models capable of providing either 8, 20, or 32 channels respectively. Enobio are portable EEG monitoring devices of 8, 20, and 32 channels intended for use in clinical patient monitoring for use in hospitals and other medical environments. The Enobio is intended to acquire, store, transmit and display electrophysiological signals as an aid in diagnostics. The system digitizes analogue EEG signals collected by a cap with electrodes and uses WiFi connectivity to transmit the EEG data to a dedicated host computer with the software. This device is intended to be used by trained health-care personnel. It is restricted to sale by or on order of a physician.

Indications for Use Comparison (21 CFR 807.92(a)(5))

The indications for use of the subject device are changed from those cleared under 510(k) K162681. The wording has been rearranged in order to align the first introductory sentence with the wording of the approved intended use statements in other territories. The modifications submitted in this 510(k) are: addition of Holter Mode for autonomous recording (i.e., recording while independent or not connected to host computer), dual-cell

battery configuration to add power capability, and TCP/TLS secure communication/ information transfer. These different technological characteristics do not change the intended use, nor do they introduce new clinical applications, modify the intended patient population, or the intended use environment or intended users. The changes to the previously cleared device do not include the replacement of user operation with automation; the changes simply create a mode where execution of a protocol is managed by the device's embedded firmware rather than by the desktop software application. There are no algorithmic or data processing modifications involved.

The NIC-EnobioDx software and device's embedded firmware updates enable the already supported EEG recording protocols to be autonomously executed. The modification changes where data is stored and how protocol execution is managed, but does not alter the clinical purpose of the device or the type of signals acquired. The modification allows the EEG data to be acquired and stored directly on the Necbox's SD card without requiring a continuous connection to a host computer.

TCP/TLS communication enables secure data streaming to authorized, within-network third-party software applications that include features for EEG review—such as filtering, annotating, zooming, and selection—as well as tools for conducting spectral-based analyses. No new diagnostic or analytic functions are introduced. The Enobio Dx device itself does not independently connect to external networks.

The dual-cell battery configuration increases operating duration only. It does not affect signal acquisition, intended patient population, or clinical purpose.

The current IFU wording reflects a minor editorial restructuring of the indications text relative to K162681 that occurred during routine maintenance updates prior to this submission. The clinical purpose, patient population, intended users, and use environment are identical to those cleared under K162681.

A high-level comparison of intended use is provided in **Table 1** below.

Table 1. Intended Use Comparison

Characteristic	Predicate Device K162681	Subject Device K261604	Discussion
Regulation Number	21 CFR 882.1400	21 CFR 882.1400	Same
Regulation Name	Electroencephalograph	Electroencephalograph	Same
Regulatory Class	II	II	Same
Product Code(s)	GWQ, GXY	GWQ, GXY, GWL	Same
Indications for Use	ENOBIO is an EEG portable monitoring device of 8, 20, 32 channels intended for the use in clinical patient monitoring for use in hospitals and other medical environments. The Enobio is intended to acquire, store, transmit and display electrophysiological signals in wireless mode as an aid in diagnostics. The system digitizes analogue EEG signals collected by a cap with electrodes, amplifies them, and uses WiFi connectivity to transmit the EEG data to a dedicated host computer with the software. This device is intended to be used by trained health-care personnel. It is restricted to sale by or on order of a physician	Enobio Dx is a wireless, battery-operated, and portable electrophysiology sensor system for the recording of electroencephalograms (EEG). Enobio Dx is available in three different models capable of providing either 8, 20, or 32 channels respectively. Enobio are portable EEG monitoring devices of 8, 20, and 32 channels intended for use in clinical patient monitoring for use in hospitals and other medical environments The Enobio is intended to acquire, store, transmit and display electrophysiological signals as an aid in diagnostics. The system digitizes analogue EEG signals collected by a cap with electrodes and uses WiFi connectivity to transmit the EEG data to a dedicated host computer with the software. This device is intended to be used by trained health-care personnel. It is restricted to sale by or on order of a physician.	Same Differences in wording reflects current IFU restructuring; intended use and clinical purpose are unchanged from K162681.
Intended patient population	Adults and children	Adults and children	Same
Intended users	Trained healthcare professionals	Trained healthcare professionals	Same
Intended use environment	Hospitals and other medical environments	Hospitals and other medical environments	Same

Technological Comparison (21 CFR 807.92(a)(6))

The predicate device and the subject device share the same core technological characteristics related to EEG signal acquisition and recording, including the fundamental principles by which EEG signals are acquired and recorded, and the system architecture

in which the EEG recorder is used in conjunction with host software for configuration, visualization, and data management.

The subject device incorporates the following technological differences relative to the predicate device:

1. A software-enabled autonomous recording mode (“Holter Mode”) through updates to the host software and embedded firmware. The SD card slot and associated hardware were present in the previously cleared device. The modification enables user configuration of recording timing and duration through the software and autonomous execution of the recording protocol by the device firmware. In Holter Mode, acquisition parameters are configured through the host software prior to recording, after which the device operates autonomously according to the defined protocol. This modification changes where data is stored and how protocol execution is managed, but does not alter the EEG signal acquisition characteristics, the type of signals recorded, or the clinical purpose of the device. No new algorithmic or data processing functions are introduced. This difference does not raise different questions of safety or effectiveness.
2. An internal battery configuration update from a single-cell to a dual-cell parallel configuration, with a corresponding adjustment to the height of the outer enclosure. The battery chemistry, charging circuitry, and protection mechanisms are unchanged. The dual-cell configuration increases operating duration only. Electrical safety was reassessed for the updated configuration and compliance with applicable standards was confirmed. This difference does not raise different questions of safety or effectiveness.
3. Additional secure data communication capabilities implemented in the host software using TCP with Transport Layer Security (TLS), enabling authenticated and encrypted communication between NIC-EnobioDx and authorized third-party applications. No new diagnostic or analytic functions are introduced. The Enobio Dx device itself does not independently connect to external networks. Cybersecurity risks were assessed and appropriate controls including authentication, access control, and encrypted communication were implemented

and verified. This difference does not raise different questions of safety or effectiveness.

Based on this comparison, the technological differences between the subject device and the predicate device do not raise new questions of safety or effectiveness.

A comparison of the technological characteristics of the predicate and subject devices is provided in the **Table 2** below.

Table 2. Technological Characteristics

Technological Characteristic	**Predicate Device K162681**	**Subject Device K261604**	**Discussion**
System components	Necbox, Software, electrode cables, electrodes and Electrode positioners	Necbox, Software, electrode cables, electrodes and Electrode positioners	Same
Fundamental EEG acquisition principles	EEG signals are acquired through the connection of Ag/AgCl electrodes to the scalp of the patient in predefined positions. The signals are transported across the electrode cables and delivered to the Necbox. Internal circuitry in the Necbox provides signal conditioning (filtering and amplification) and analog-to-digital conversion. Digital data is received and processed by the embedded microcontroller. Measurement parameters are: ● Sampling Rate = 500 SPS ● Bandwidth = 0-125Hz (DC Coupled) ● Resolution =	EEG signals are acquired through the connection of Ag/AgCl electrodes to the scalp of the patient in predefined positions. The signals are transported across the electrode cables and delivered to the Necbox. Internal circuitry in the Necbox provides signal conditioning (filtering and amplification) and analog-to-digital conversion. Digital data is received and processed by the embedded microcontroller. Measurement parameters are: ● Sampling Rate = 500 SPS ● Bandwidth = 0-125Hz (DC Coupled) ● Resolution =	Same

Technological Characteristic	Predicate Device K162681	Subject Device K261604	Discussion
	24 bits - 0.05µV ● Noise = <1µV RMS	24 bits - 0.05µV ● Noise = <1µV RMS	
EEG data type and recording function	The NIC-EnobioDx software controls execution of EEG recording protocols. A protocol, as defined in the software user interface, consists of a duration for the recording and the assignment of head positions in the international 10-10 EEG montage system to recording channels on the device. Protocols are executed by the NIC-EnobioDx software, which commands the Necbox to start and stop recording on specific channels as configured by the protocol. During execution, the Necbox continually sends EEG data for all active channels back to the host computer, where NIC-EnobioDx processes it for display and storage in files. Numerous file formats are supported, both proprietary and standard.	The NIC-EnobioDx software is capable of controlling the execution of EEG recording protocols. Alternatively, the NIC-EnobioDx software may command the Dennis Firmware running on the Necbox's microcontroller to execute an EEG recording protocol autonomously without a continuous connection to the NIC-EnobioDx software required. In both cases the characteristics of the EEG acquisition remain the same. The difference is in the location of the stored data (host computer vs. Necbox SD card) and in the management of the recording protocol; essentially the starting and stopping time of the recorded data.	Both devices control the execution of EEG recording, but the subject device includes an autonomous storage of data
Channels / models	8 / 20 / 32	8 / 20 / 32	Same
Materials	Common-use thermoplastics, printed circuit boards, off-the-	Common-use thermoplastics, printed circuit boards, off-the-	Same

Technological Characteristic	Predicate Device K162681	Subject Device K261604	Discussion
	shelf electronic components, lithium polymer battery pack, adhesives and labelling.	shelf electronic components, lithium polymer battery pack, adhesives and labelling.	
Data storage method	Host computer-based storage	Host computer-based + autonomous SD storage (Holter Mode)	Addition of a new storage method
Power source / battery	Internal battery (single-cell configuration)	Internal battery (Dual-cell parallel configuration)	Different
Enclosure (Case)	Portable enclosure	Portable enclosure (adjusted for increased battery capacity)	Different
External Data communication Interface	Host-computer file system	Host-computer file system and/or TCP/TLS communication	Different

The technological differences identified above do not raise new questions of safety or effectiveness.

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

Performance testing activities were conducted to evaluate the impact of the proposed software, firmware, and hardware modifications on the performance of the Enobio Dx system. All design verification and validation activities were completed prior to this submission and the results demonstrated that the predetermined acceptance criteria were met for each of the three modifications.

Testing activities included: functional verification and validation of Holter Mode autonomous EEG recording functionality including data integrity and recording start conditions; electrical verification and mechanical testing of the dual-cell battery configuration including charging behavior, enclosure integrity, and drop testing; and

cybersecurity verification of the TCP/TLS communication implementation including authentication evaluation, encryption evaluation, static code analysis, and penetration testing conducted by an independent third party.

The battery incorporated into the modified Enobio device was evaluated in accordance with IEC 62133-2:2017+A1:2021. Compliance assessment included Clause 4 (Parameter Measurement Tolerances), Clause 5 (General Safety Considerations, including insulation and wiring, venting, temperature/voltage/current management, terminal contacts, assembly of cells into batteries, quality plan and battery safety components), Clause 6 (Type Test and Sample Size), Clause 7 (Specific Requirements and Tests), Clause 8 (Information for Safety), Clause 9 (Marking), and Clause 10 (Packaging and Transport). The safety testing performed included subclauses 5.2 Insulation Resistance, 7.2.1 Continuous Charging at Constant Voltage, 7.2.2 Case Stress at High Ambient Temperature, 7.3.1 External Short Circuit (Cell), 7.3.2 External Short Circuit (Battery), 7.3.3 Free Fall, 7.3.4 Thermal Abuse, 7.3.5 Crush, 7.3.6 Over-Charging of Battery, 7.3.7 Forced Discharge, 7.3.8.1 Vibration, 7.3.8.2 Mechanical Shock, and 7.3.9 Forced Internal Short-Circuit Design Evaluation. Information for safety, marking, and packaging requirements were also evaluated under Clauses 8, 9, and 10, respectively. All applicable requirements were met and the battery passed all applicable tests.

Following implementation of the changes described in this submission, the device continues to perform according to its specified requirements. No clinical investigations were conducted or required for this submission, as the modifications do not alter the intended use or fundamental scientific technology of the device.