November 25, 2025

NaoX Technologies SAS
John Pappan
Regulatory Consultant
62 rue Mazarine
Paris, 75006
France

Re: K251550
Trade/Device Name: NX01 (nx01)
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMC
Dated: May 16, 2025
Received: May 21, 2025

Dear John Pappan:

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,

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)*
K251550

Device Name
NX01 (NX01)

Indications for Use *(Describe)*
NX01 is intended for use in healthcare or home settings to acquire, record, and transmit electrical activity of the brain by placing non-invasive electrodes in the ears of patients. It acquires, records and transmits one channel of electroencephalogram (EEG) data. The medical use of data acquired by NX01 is to be performed under the direction and interpretation of a licensed medical professional. NX01 does not provide any diagnostic conclusions about the patient's condition.

The NX01 is intended for use with adult and pediatric patients (6+).

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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TRADITIONAL 510(k) PRE-MARKET NOTIFICATION

NAOX Technologies

NX01

May 16th, 2025

Table of Contents

1. Administrative information

Table 1 – Information of the manufacturer, contact person and product

Manufacturer	
Official name	NAOX Technologies SAS
Trade name	NAOX Technologies
Address	62 rue Mazarine 75006 Paris
Country	France
Contact Person	
Name	John Pappan
Title/Job	Regulatory Consultant
Phone number	1.718.964.3406
Email address	john@jpglobalenterprise.com
Product	
Trade Name	NX01
Common Name	EEG Monitor
Classification	Reduced-Montage Standard Electroencephalograph (Class II)
Product Code	OMC
Regulation Number	21 CFR 882.1400

2. Company introduction

NaoX Technologies is a start-up which designs, manufactures, and sells innovative earbuds to measure in-ear Electroencephalography (in-ear EEG) over long periods of time, in hospitals and ambulatory healthcare.

3. Definitions and abbreviations

Table 2 – Terms and concepts used throughout the document.

Abbreviation	Definition
EEG	Electroencephalography
BLE	Bluetooth Low Energy
HCP	Healthcare Provider
LED	Light Emitting Diode
EDF	European Data Format

4. Intended use/Indications for Use

NX01 is intended for use in healthcare or home settings to acquire, record, and transmit electrical activity of the brain by placing non-invasive electrodes in the ears of patients. It acquires, records and transmits one channel of electroencephalogram (EEG) data. The medical use of data acquired by NX01 is to be performed under the direction and interpretation of a licensed medical professional. NX01 does not provide any diagnostic conclusions about the patient's condition.

The NX01 is intended for use with adult and pediatric patients (6+).

5. Device description

NX01 is a wearable device for continuous recording of non-invasive EEG signals in healthcare and home settings. NX01 is intended to be prescribed by a trained healthcare professional. It consists of a pair of earbuds (one per ear) integrating a pair of active, dry electrodes, connected by a cable to a command panel. This command panel houses the battery, the internal memory to store the data, the main acquisition unit with function buttons and LEDs which display the device's status.

The NX01 solution is composed of :

- Two earbuds (1) connected by 45 cm cables, to a command panel (5). This command panel houses the battery, the internal memory to store the data, the main acquisition unit with function buttons (2 - Left button and 3 - Right button) and LEDs (4) which display the device's status.

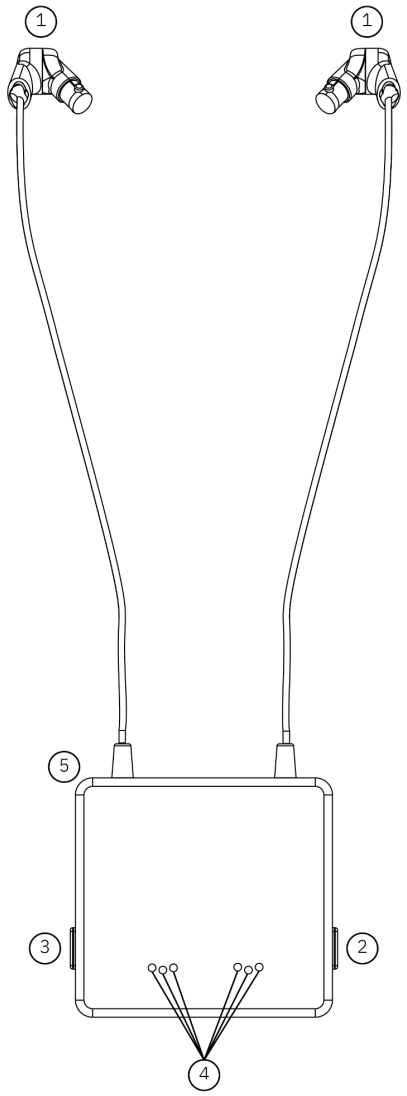

Figure 1: NX01 Device

A set of eartips, to be placed on the earbuds for the recording. Eartips are single use consumable that should be discarded and replaced for every recording that takes place.

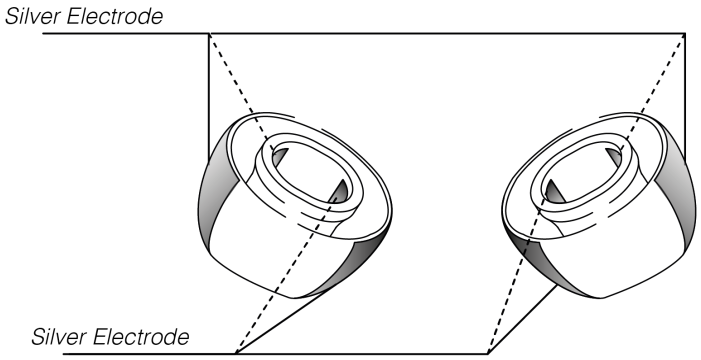

Figure 2: NX01 Eartips

- A medical grade PSU with the following specifications:

Input	AC 100-240V, 50/60Hz
Output	USB-C DC 5.0V, min 1.0A
Compliance	IEC 60601-1, IEC 62368-1 or IEC 60950-1

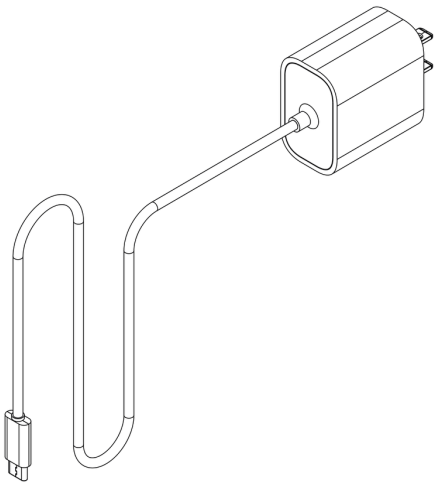

Figure 3: NX01 Charger

6. Predicate Devices

Information about the Primary Predicate device for EEG equipment is presented in Table 3 as follows:

Table 3 – Primary Predicate device

Predicate Device	
Tradename	Byteflies Kit
510(k)	K192549
Regulation number	21 CFR 882.1400
Regulation Name	Electroencephalograph
Product Code	OMC
Class	Class II

Additional information on the substantial equivalence with the Primary Predicate Device is provided in Table 5.

7. Substantial Equivalence Comparison

Comparison to Primary Predicate Device

The NX01 is technologically equivalent to other reduced EEG monitoring devices, specifically to our predicate device Byteflies. The NX01 and predicate devices are wearable systems that acquire analog EEG signals in a reduced montage, digitize the sample-level signals, and save them for later interpretation by a healthcare professional. Both systems are powered by low-voltage batteries, making them safe for use in patients.

In general terms, the Byteflies Kit records brain activity through two EEG channels in a bipolar configuration using non-invasive conventional DIN 42802 electrode connectors. The NX01 system records the brain activity through a single EEG channel in a bipolar configuration using non-invasive and biocompatible silver active and dry electrodes integrated into 2 earbuds.

In addition, while the Byteflies kit is not intended for a particular population with a specific age range, the NX01 is intended only for adult and pediatric patients 6 years and older. The

difference with the Byteflies kit can be explained by the fact that the NX01 system integrates earbuds with the EEG electrodes as part of the medical device, which are designed for ear sizes of the intended pediatric and adult population. In contrast, the Byteflies Kit uses conventional DIN 42802 electrode connectors, which can be connected to a wide variety of electrode sizes and shapes.

Based on the results from our extensive testing, we believe that our device does not raise new safety or effectiveness concerns.

The table below summarizes the technological characteristics of the Byteflies Kit in comparison to the subject device.

Table 5 – Comparison with Primary Predicate device

	NX01 **(Subject Device)**	**Byteflies Kit** **(Primary Predicate Device)**	**Discussion**
Indications for Use	NX01 is intended for use in healthcare or home settings to acquire, record, and transmit electrical activity of the brain by placing non-invasive electrodes in the ears of patients. It acquires, records and transmits one channel of electroencephalogram (EEG) data. The medical use of data acquired by NX01 is to be performed under the direction and interpretation of a licensed medical professional. NX01 does not provide any diagnostic conclusions about the patient's condition.	The Byteflies Kit is intended for prescription use in the home, healthcare facility, or clinical research environment to acquire, record, and transmit electrical activity of the brain by placing non-invasive electrodes on the head of patients. It acquires, records and transmits two channels of electroencephalogram (EEG) data. The medical use of data acquired by the Byteflies Kit is to be performed under the direction and interpretation of a licensed medical professional. The Byteflies Kit does not provide any diagnostic conclusions about the patient's condition.	Signal Type: **EQUIVALENT** Both devices record a reduced EEG montage via noninvasive electrodes placed on the head for the predicate device and in the ears for the subject device. Environment: **EQUIVALENT** Both devices are indicated for use in healthcare and home or ambulatory environments. Medical Use: **EQUIVALENT** Both devices record raw EEG data and make this available to a healthcare professional for further interpretation; neither device provides any diagnostic claims about the subject's condition. Intended population:

			NO SIGNIFICANT DIFFERENCE While the Byteflies kit is not intended for a particular population with a specific age range, the NX01 is intended only for adult and pediatric patients 6 years and older. The difference with the Byteflies kit can be explained by the fact that the NX01 system integrates earbuds with the EEG electrodes as part of the medical device, which are designed for ear sizes of the intended pediatric and adult population. In contrast, the Byteflies Kit uses conventional DIN 42802 electrode connectors, which can be connected to a wide variety of electrode sizes and shapes.
Physiological Signal Acquired	EEG	EEG	**EQUIVALENT** Same physiological signal for both devices.
Environment of Use	Healthcare and home settings.	Home (data acquisition), Healthcare and Clinical Research Facility (data acquisition, device configuration, and data retrieval).	**EQUIVALENT** Both devices are intended for healthcare and home settings. The predicate device is also intended for the Clinical Research Facility. This difference does not raise questions on the subject device's effectiveness or safety.
Power Source	Z52H Li-ion button cell rechargeable battery compliant to IEC 62133-1 and UN 38.3.	Li-Ion battery (Sensor Dot) and a certified Class II AC/DC power supply (Docking Station).	**EQUIVALENT** The component of the predicate device that is carried by the patient is battery powered. The entire subject device is

			powered by a low voltage battery.
System Components	A command panel connected by a cable to a pair of earbuds (one per ear) integrating active, dry EEG electrodes.	Sensor Dot, Sensor Patch, Docking Station	**EQUIVALENT** All devices consist of: - a sensor module that contains or allows the connection of EEG electrodes interfacing with the patient (Earbuds for the subject device and Sensor Patch for the predicate device). - a main acquisition module that acquires and locally stores raw EEG signals (a command panel for the subject device and Sensor Dot+Docking Station for the Byteflies kit).
Stored EEG data available	European Data Format (.edf) which can be accessed wirelessly via Bluetooth.	Sample-level EEG as text file which can be accessed via the Docking Station.	**NO SIGNIFICANT DIFFERENCE** Both devices generate output files with sample-level EEG data, in text format for the predicate device and in .edf format for the subject device. Edf file is a standard format for EEG data storage that can be opened with several FDA-cleared EEG software such as Curry (K001781) or Persyst (K222002).
EEG Channels	1 bipolar EEG channel.	Up to 2 bipolar EEG channels.	**NO SIGNIFICANT DIFFERENCE** Both devices record a reduced EEG montage in a bipolar configuration. However, while the Byteflies kit can record any bipolar derivation from the 10-20 system, the subject device is restricted to one pair of electrodes in the earbuds that can record an EEG signal similar to the

			T7-T8 bipolar derivation from the 10-20 EEG positioning system. In the case of the subject device, this difference, compared with the predicate device, is intrinsic to the design requirement of recording EEG activities from sensors in the ears through conventional earbuds, which can facilitate and simplify the monitoring of brain activities in several contexts. Further evidence supporting the substantial equivalence between EEG signals recorded with the predicate device through the T7-T8 bipolar derivation and the subject device was provided in a clinical study.
Contains patient isolation	Powered by a low-voltage rechargeable battery, thus no connection between the patient and mains.	Sensor Dot is battery powered, thus no connection between patient and mains. The Docking Station is powered by a certified Class II AC/DC medical power supply and contains no AC wiring.	**EQUIVALENT** The component of the predicate device that is carried by the patient is low-voltage battery powered. The entire subject device is also powered by a low-voltage battery.
Continuous maximum recording time	10 hours.	24 hours.	**DIFFERENT** Although the subject device can record EEG data for less continuous time than the predicate device, this does not impact its effectiveness or safety. This difference is explained by a design requirement in which we minimized the size and weight of the subject device to obtain

			the smallest and lightest possible system. This is achieved in part by reducing the size of the rechargeable battery, which in turn decreases the duration of the continuous maximum recording time. This optimized design ensures maximum comfort, allowing the user to wear the device for several hours uninterrupted for meaningful long-term monitoring.
User Interface	Yes, LEDs to ensure signal quality monitoring and proper operation. Also, the command panel has two push buttons for basic device operation.	Yes, LEDs to ensure proper system connection and operation. Also the Docking Station provides a reset button.	**EQUIVALENT** Both devices incorporate on-hardware LEDs that provide users with feedback on their operation. The two of them also offer push buttons for additional user interaction.
Software/System User Interface	The NX01 is not associated with any data viewer software.	The Byteflies Kit contains no data viewer software.	**EQUIVALENT** Both devices are not associated with any data viewer software.
Biocompatibility	Biocompatibility of patient contacting components compliant to ISO 10993-1, Irritation and Skin Sensitization compliant to ISO 10993-10, Cytotoxicity compliant to ISO 10993-5	All external parts were tested according to ISO 10993 (Cytotoxicity – ISO 10993-5, Sensitization – ISO 10993-10, and Skin Irritation – ISO 10993-10)	**EQUIVALENT** Both devices are compliant with the same standards for Biocompatibility.
Electrical Safety and Electromagnetic Compatibility	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-1-6 IEC 80601-2-26	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-1-8 IEC 60601-1-6 IEC 60601-2-26	**EQUIVALENT** Both devices are compliant with the same standards for Electrical Safety and Electromagnetic Compatibility. In the case of the subject device, the IEC 80601-2-26:2019 standard cancels and replaces the third edition of IEC 60601-2-26

			published in 2012. The standard IEC 60601-1-8 does not apply to the subject device as it does not correspond to an alarm system.
Regulatory	Product Code OMC 21 CFR 882.1400	Product Code OMC 21 CFR 882.1400	**EQUIVALENT** Both devices share the same primary OMC product code corresponding to a reduced-montage standard electroencephalograph.

In accordance with the information displayed in the table above, the differences between NX01 and its predicate devices do not raise new questions of safety and effectiveness, and therefore we consider that they are substantially equivalent.

8. Non-clinical Testing - Performance Testing

Design, verification and usability tests were performed on the NX01 as a result of the risk analysis and product requirements. Human factors testing was conducted to evaluate tasks associated with use of the device. Independent UL-certified laboratory testing demonstrated that the NX01 meets the requirements of IEC 60601-1 and IEC 60601-1-11 for electrical safety, and IEC 60601-1-2 for electromagnetic compatibility. The NX01 complies with the particular requirements of IEC 80601-2-26 for safety and performance of electroencephalographs. Finally, it meets all applicable requirements of ISO 10993, IEC 60601-1-6.

Additionally, Naox has performed testing of dry electrode input buffers (modified IEC 60601-2-26 testing).

The Table 7 below provides the complete list of standards that are used in the 510(k) to establish device performance and support substantial equivalence:

Table 7 – List of compliant standards

Standard designation and version	**Standard Name**	**Scope**	**Recognition Number**	**Deviations**
ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance	Complete standard	19-46	None
IEC 60601-1-2 Ed4.1 2020-09	Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests	Complete standard	19-36	None
HA60601-1-11:2015 [Including AMD1:2021]	Medical Electrical Equipment - Part 1-11: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment	Complete standard	19-47	None
IEC 80601-2-26 : 2019	Medical Electrical Equipment - Part 2-26: Particular Requirements for the Basic Safety and Essential Performance of	Partial (Excluding sections on	N/A	Deviation on the essential performance for

	Electroencephalographs	impedance-based contact monitoring)		input noise and common mode rejection
ISO 10993-1 Ed5 2018-08	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process	Complete standard, with emphasis on biocompatibility testing for materials in contact with the patient	2-258	None
ISO 10993-5 Ed3 2009-06	Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity	Complete standard	2-245	None
ISO 10993-10 Ed4 2021-11	Biological Evaluation of Medical Devices - Part 10: Tests for Skin Sensitization	Complete standard	2-296	None
ISO 10993-23 Ed1 2021-01	Biological evaluation of medical devices Part 23: Tests for irritation	Complete standard	2-291	None
IEC 62133 Ed2 2012-12	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications	Complete standard	19-13	None
UN 38.3	Recommendations on the Transport of Dangerous Goods - Manual of Tests and Criteria - Section 38.3: Lithium Batteries	Complete standard	N/A	None
IEC 62366-1 Ed1.1 2020-06	Medical Devices – Part 1: Application of Usability Engineering to Medical Devices	Complete standard	5-129	None
IEC 60601-1-6 Ed3.2 2020-07	Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability	Complete standard	5-132	None
IEC 62304 Ed1.1 2015-06	Medical device software — Software life cycle processes	Complete standard	13-79	None
IEC 82304-1 Ed1 2016-10	Health software Part 1: General requirements for product safety	Complete standard	13-97	None
IEC 81001-5-1 Ed1 2021-12	Health software and health IT systems safety, effectiveness and security Part 5-1: Security — Activities in the product life cycle	Partial	13-122	None

IEEE 2010-2023	Recommended Practice for Electroencephalography (EEG) Neurofeedback Systems	Partial	17-18	None

9. Clinical Tests

A multi-center clinical study designed in accordance with FDA recommendations and good clinical practice principles, encompassing healthy volunteers, patients with epilepsy, and hardware-in-the-loop (HIL) simulations has been performed on NX01.

Experiments were conducted across diverse international settings, including clinical sites in Warsaw, Poland, and Bogotá, Colombia, as well as laboratory facilities in Paris, France for the HIL testing.

NX01 performance was assessed compared to reference EEG systems:

- Studies involving healthy subjects were performed in both controlled sleep laboratories and participants' homes, simulating naturalistic usage conditions, using NX01 and Byteflies Kit. Healthy participants underwent structured protocols that included resting state recordings (eyes open/closed), artifact-inducing tasks (e.g., eye movements, speech, jaw clenching), and overnight sleep monitoring.
- In subjects with epilepsy, the focus was on the quantitative comparison between interictal epileptiform discharges (IEDs) recorded concurrently between the NX01 device and gold-standard clinical EEG systems.
- In the HIL arm, pre-recorded EEG signals from public epilepsy datasets were replayed in real-time through a compliant EEG emulator system. These signals were simultaneously captured by both the NX01 device and the Byteflies Kit, allowing a clean, reproducible environment for pairwise comparison under identical input conditions.

The evidence gathered supports that the NX01 device provides reasonable assurance of safety and effectiveness. Across multiple study arms—including healthy participants, patients with epilepsy, and Hardware-in-the-Loop simulations—the device consistently met or exceeded all pre-specified performance endpoints without safety concerns or adverse user experiences.

10. Substantial Equivalence Conclusion

The subject device has the same intended use and incorporates the same fundamental technology as the legally marketed predicate device to which it was compared. Based on intended use, technological characteristics, and performance testing to account for differences in technological characteristics as compared to the predicate, it can be concluded that the subject device, NX01, is substantially equivalent to the identified predicate device.