October 11, 2024

QX World Ltd
Lilla Strobel
QA Advisor
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Budapest, Hungary 1095
Hungary

Re: K232779
Trade/Device Name: Quex Ed; Quex S
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMC, GZO
Dated: September 11, 2024
Received: September 11, 2024

Dear Lilla Strobel:

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232779

Device Name
QUEX ED and S

Indications for Use *(Describe)*

The QUEX ED and QUEX S device is indicated for use as an Electrophysiological System. The Electrophysiological System is made up of the following Items which are functions of the QUEX ED and S device:
1. Two channel EEG:
The QUEX ED and S Device is intended to record and store EEG signals, and to present the EEG signals in visual formats in real time. The visual signals assist trained medical staff to make neurological diagnoses. The EEG device does not provide any diagnoses conclusion about the subject's condition and does not provide any automated alerts of an adverse clinical event. The QUEX ED AND S Device is intended to be used in a professional healthcare facility environment.
2. GSR [galvanic skin response measuring]
The QUEX ED and S device is intended for use by trained healthcare professionals, to detect and monitor electrical signals produced by the body skin conductance by using electrodes placed on the skin.

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 information:

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Device:

Name of Device:
1) QUEX ED Electrophysiological Device
2) QUEX S Electrophysiological Device
Common or Usual Name: Electrophysiological Device
Classification Name: reduced- montage standard electroencephalograph, electroencephalograph (21 CFR 882.1400)
Regulatory Class: II
Product Code: OMC, GZO

Predicate device

Manufacturer: Neurosteer Inc. Neurosteer EEG Recorder (K221563)

Device Description

Device identification:

QUEX ED or QUEX S devices are contains the following components:

- QUEX ED or QUEX S hardware.
- QUEX Monitor software
- USB – USB cable for data communication and power supply.
- EEG electrodes (head electrodes)
- Electrodes for GSR measurements (limbs)
- Cable harnesses for head and limbs.

The QUEX Monitor software is exclusively used for QUEX ED and QUEX S as part of the system.

The EEG electrodes and the electrodes used for GSR measurements are connected to the QUEX ED or S devices. The device makes the necessary gain on the analog signals and digitalize the signals. The digitalized information is acquired and displayed by the QUEX Monitor software. The QUEX monitor software can run on PCs, notebooks with Windows OS.

Electroencephalography (EEG), measures brain wave activity. The system uses the head harness and electrodes to acquire the signals. The QUEX Devices are measures brain activity on two channels. The EEG wave recording electrodes are connected to the forehead with dry electrodes.
The galvanic skin response (GSR, which falls under the umbrella term of electrodermal activity, or EDA) refers to changes in sweat gland activity.
The GSR recording is done via limb electrodes attached to the wrists and ankles.

Device characteristics:

EEG

- Two channel EEG
- Measurement on the scalp
- 10 μV to 100 μV signal measurement

GSR (Galvanic Skin Response)

- skin conductance change measurement effected by changes by sweat gland activity,
- measurement with DC current for skin resistance,
- measuring range: 1 Kohm – 1 Mohm,

Environment:

The device to be used in professional healthcare environment.

Indications for use

The QUEX ED and S device is indicated for use as an Electrophysiological System. The Electrophysiological System is made up of the following Items which are functions of the QUEX ED and S device:

1. Two channel EEG:

The QUEX ED and S Device is intended to record and store EEG signals, and to present the EEG signals in visual formats in real time. The visual signals assist trained medical staff to make neurological diagnoses. The EEG device does not any diagnoses conclusion about the subject's condition and does not provide any automated alerts of an adverse clinical event. The QUEX ED and S Device is intended to be used in a professional healthcare facility environment.

2. GSR [galvanic skin response measuring]

The QUEX ED and S device is intended for use by trained healthcare professionals, to detect and monitor electrical signals produced by the body skin conductance by using electrodes placed on the skin.

Intended user:
Professional use (Therapist)

The device itself does not generate any stimulation to the patient. External visual, audible, or other stimulation shall be used based on the trained operator (physician) decision. The QX Word does not take the responsibility of the possible adverse effect of an external stimulation.

Technical specification of QUEX ED and QUEX S Electrophysiological Device

Electrical characteristics	
Voltage [power supply]	5V DC (Port USB)
Maximum consumption	1200 mA
Time to change the signal	Max. 300 ms
Time to change the channel	Max. 100 ms
Rated output current	Max. 1 mA
EEG Characteristics	
Digital sampling rate per channel	Programable
Calibration signals	programable, 0-200 µV
Number of channels	2
EEG channel characteristics	1. No. of channels: 2 2. A/D Conversion: 8 bit ADC 3. Max Sampling Rate: 1ms 4. Sensitivity: User definable 10 µv/mm, 20 µv/mm, 100 µv/mm 5. LP filter: 0 - 100 Hz (8 degree digital filter) 6. Notch Filter: 50/60 Hz 7. Input impedance: > 10 M ohm 8. CMRR: > 100 µV 9. Noise level : < 5 µV RMS
accuracy of signal reproduction;	difference less than ±20 % acc to IEC 80601-2-26, 201.12.1.102
input dynamic range and maximum offset voltage	less than ±10 % acc to IEC 80601-2-26, 201.12.1.103
frequency range and bandwidth	0,5 Hz – 50 Hz, relative output within 71% to 110% of the output at 5Hz
a description of waveform displays	EEG signals are displayed
Skin resitance	
Galvanic Skin Response data acquisition Output Voltage	Measurement Range: 1k - 1MΩ +/- 10% 0 – 4 V DC

Comparison with predicate device

The QUEX ED and QUEX S EEG and GSR recorder and the predicate devices have the same intended use and very similar technological features, including software intended for recording and viewing EEG signals. The differences between the Neurosteer EEG Recorder and QUEX ED and QUEX S devices raise no new issues of safety or effectiveness. Performance testing confirms that the device functions as intended, supporting substantial equivalence. The characteristics of the subject and predicate device are summarized in the following table:

Attribute	Predicate Device: Neurosteer EEG Recorder (K221563)	QUEX ED and QUEX S EEG and GSR devcice	Comparison
Device class and regulation	Class II per 882.1400	Class II per 882.1400	Same
Product codes	OMC	OMC, GZO	Same.
Indications for use	The Neurosteer EEG Recorder is intended to record and store EEG signals, and to present the EEG signals in visual formats in real time. The visual signals assist trained medical staff to make neurological diagnoses. The EEG Recorder does not provide any diagnostic conclusion about the subject's condition and does not provide any automated alerts of an adverse clinical event. The EEG Recorder is intended to be used in a professional healthcare facility environment.	1. Two channel EEG: The QUEX ED Device is intended to record and store EEG signals, and to present the EEG signals in visual formats in real time. The visual signals assist trained medical staff to make neurological diagnoses. The EEG device does not any diagnoses conclusion about the subject's condition and does not provide any automated alerts of an adverse clinical event. The QUEX ED Device is intended to be used in a professional healthcare facility environment. 2. GSR [galvanic skin response measuring resistance] The QUEX ED device is intended for use by trained healthcare professionals, to use of sensors or electrodes placed on the skin to detect and monitor electrical signals produced by the body skin conductance. The GSR measurement function is 510(k) exempt.	Substantially equivalent

Classification	Review Panel Neurology Product Code OMC Regulation Number 882.1400 ***Device Class 2*** ***Submission Type 510(k)***	Review Panel Neurology Product Code OMC Regulation Number 882.1400 ***Device Class 2*** ***Submission Type 510(k)*** Device Galvanic Skin Response Measurement Review Panel Neurology Product Code GZO Regulation Number 882.1540 ***Device Class 2*** ***Submission Type 510(K) Exempt***	
System components	EEG electrodes with conductive hydrogel EEG sensor Portable EEG monitor to display EEG data in real time in visual format and transfer EEG recording files to cloud storage platform via internet connection Cloud storage platform Browser-based EEG viewing software	EEG electrodes with cables and securing strips. Main box for acquiring and digitalizing the analog physiological signals as EEG and skin resistance for GSR. Application-based EEG viewing software running on desktop and laptops	Substantially equivalent
Measurement of physiological data	EEG recording only	EEG and GSR recording	Substantially equivalent GSR function is 510(k) exempt
Channels	1	2	Substantially equivalent
EEG presentation format(s)	Visual only (raw EEG waveform, spectrogram, metrics and bar graph views)	Visual only (raw EEF waveform)	Substantially equivalent
Data transfer method(s)	Bluetooth 2.4 GHz and internet connection (ethernet or Wi-Fi)	USB cable,	No additional risk to patient, more reliable connection.
Data file format	Edf		Same
Type of use	Reusable	Reusable	Same
Power source	Lithium polymer battery – rechargeable with 100-240 V AC power adapter (device does not work when connected to AC to recharge)	USB connected to a computer, 5V DC, to be used IEC 62368 compliance computer.	Same level of electrical safety. No risk from the lithium battery in the device.

Charging	Micro-USB charging cable; if connected to a computer, all EEG acquisition functions are automatically disabled	No charging is necessary, to be used charged laptops or computer connected to mains supply.	Substantially equivalent, no risk from the battery exhausting.
Electrode type	Passive silver/silver-chloride (Ag/AgCl)		Same
Number / locations of electrodes	3 (Locations: Fp1, Fpz, Fp2)	5 (Fp1:F7; Fp2:F8; Fpz)	Substantially equivalent
Conductive electrolyte gel	Semi-solid hydrogel is included in a layer integrated into each electrode assembly.		Substantially equivalent
Patient contact	Patient forehead (intact skin)	Patient forehead (intact skin)	Same
Securing method	Integrated adhesive layer	EEG strip	Substantially equivalent
Available sizes and dimensions	One size (10.5 cm)	One size	Substantially equivalent
Type of use	Single use, non-sterile, disposable	Reusable electrodes, single use electrodes can be used	Substantially equivalent
Connector	Integrated single-cable connector to connect to an EEG recording device	The electrodes connected via connector fit for device inlets.	Same
Compatibility	Compatible with the Neurosteer EEG Recorder only	The device can be used with own software only (QUEX Monitor)	Substantially equivalent

Non-clinical tests performed:

Test	Test Method Summary	Results
Bench tests: Electrical Safety	The QUEX ED and QUEX S devices are tested according to IEC 60601-1 ed 3.1 and EN/IEC 60601-2-26 standards. Retesting was performed acc.to the most current EEG Standard: IEC 80601-2-26. the tests were performed by national accredited testing laboratories.	All samples passed the acceptance criteria. The subject device is as safe as the predicates with respect to electrical safety.
Bench tests: Electromagnetic Compatibility (EMC)	IEC 60601-1-2:2014+A1:2020 (EN 60601-1-2:2015+A1:2021): Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances - Requirements and tests IEC TS 60601-4-2:2024: Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity:	All samples passed the acceptance criteria for each test. The subject device is as safe as the predicates with respect to EMC.

	performance of medical electrical equipment and medical electrical systems The device to be used in professional healthcare environment.	
Bench tests: EEG Essential Performance	The essential performance of the QUED ED and S devices is accessed according to the EN/IEC 60601-2-26 and EN/IEC 80601-2-26.	All samples passed the acceptance criteria. The subject device is as effective as the predicates with respect to EEG performance.
Bench tests: GSR measurments	The device is tested in accordance a test plan for evaluation of the resistance measurement within the specified limits 1Kohm – 1Mohm.	The test sample is passed the tests.
Biocompatibility	510(k) approved electrodes and cables are used.	
EEG electrode performance	510(k) approved electrodes and cables are used.	

Conclusions

The QUEX ED and QUEX S has the same intended use and similar indications for use, technological characteristics, and principles of operation as the predicate devices. The minor technological differences between the QUEX ED and QUEX S and its predicate devices raise no new or different questions of safety or effectiveness. Performance data demonstrate that the QUEX ED and QUEX S r is as safe and effective as the predicate devices. Thus, the QUEX ED and QUEX S are substantially equivalent.