August 31, 2023

NeuroField Inc.
℅ Tom Renner
Quality, Efficiency & Regulatory Affairs Consultant
Vision28
915 SW Rimrock Way, STE 201 PMB 402
Redmond, OR 97756

Re: K221959
Trade/Device Name: Q21
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ
Dated: August 1, 2023
Received: August 1, 2023

Dear Tom Renner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. 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 located 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.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K221959

Device Name
Q21

Indications for Use *(Describe)*
The NeuroField Q21 System is indicated for prescription use to acquire, record, transmit, and display physiological data for electroencephalographic (EEG) studies of patients of all ages.

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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Section 5: 510(k) Summary

Contact Details

Applicant Name: NeuroField Inc.
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Bishop, CA 93514

Contact Name: Tom Renner
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Vision28
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Date Prepared: July 31, 2023

Device Name

Trade Name: Q21
Product Code: GWQ
Common and Classification Name: Electroencephalograph
Classification Regulation: 21 CFR 882.1400
Product Class: Class II

Legally Marketed Predicate Device

510(k)	Product Code	Trade Name	Applicant
K201819	GWQ	Cadwell Apollo System	Cadwell Industries, Inc. 909 North Kellogg Street Kennewick, WA 99336

Legally Marketed Secondary Predicate Device

510(k)	Product Code	Trade Name	Applicant
K192753	GWQ	NeuralScan System	Medeia, Inc. 3771 Southbrook Dr Dayton, Ohio 45430

Device Description

I. Overview

The Q21 is a 20-Channel Quantitative Electroencephalogram (QEEG) system which records 24-bit high resolution EEG data.

NeuroField EEG is the main software which runs on a Windows-based computer/laptop where basic data is collected and controls the Q21. This software records the patient information and displays and stores the EEG.

The Q21 system provides for typical EEG functions, including realtime EEG recording and viewing, adjustable vertical and horizontal display scale, adjustable highpass, lowpass, and notch filters, file import and export, offline review, the ability to show and hide individual channels, remontaging, and the ability to add event markers.

The Q21 system supports both individual electrodes and standard 19-channel Electrocap electrode arrays.

II. Major Components

Each Q21 system consists of an amplifier, software, and components of a standard personal computer (monitor, keyboard, and mouse).

The Q21 amplifier is a 19+1 channel, 24-bit, low-noise, non-multiplexed, battery-powered, optically-isolated amplifier. The "+1" channel can be used as an auxiliary physiological channel. The amplifier has an input dynamic range of ± 375 mV, and can record 256 samples per second per channel. The amplifier input impedance is greater than 1000 GΩ, and the CMRR is greater than 110dB.

III. Principles of Operation

The Q21 is a digital electroencephalograph system. During use, an Electrocap is applied to the patient using that product's provided instructions, and connected to the Q21 amplifier. The Q21 amplifier in turn is plugged into a CANBus USB adapter, which is connected to a personal computer. The NeuroField EEG software, running on that computer, controls the amplifier and displays the EEG signals.

For acquisition, the operator initiates an EEG session in NeuroField EEG. Once a session is started, the electrodes in the Electrocap detect analog changes in electrical activity. The Q21 amplifier converts the analog signals to digital signals. NeuroField EEG records the digital signals as selected by the operator and displays those signals on screen. Files are saved for later review or analysis by trained personnel.

For review, the operator opens a previous recording using NeuroField EEG. The digital signals are displayed on screen and can be manipulated and visualized in a variety of ways.

IV. Accessories

The following third-party accessories are supported for use with the Q21. These patient contacting accessories are commercially sourced, 510(k) cleared, and used without modification:

Electrocaps

E1 Electrocaps from Electro-Cap International, Inc.

3 ½" Ear Clips

E5-9SDROPS ear clips from Electro-Cap International, Inc.

Paste, Electro-Gel, Sponge Disks, Syringes, NuPrep, Swabs

Standard EEG skin-prep products are also supported, including:

- TEN 20 Paste
- Electro-Gel
- Sponge Disks
- Syringes & Blunt tip Inserts
- NuPrep
- Alcohol swabs

Intended Use/Indications for use

The NeuroField Q21 System is indicated for prescription use to acquire, record, transmit, and display physiological data for electroencephalographic (EEG) studies of patients of all ages.

Substantial Equivalence Comparison

Based upon comparisons of regulatory parameters, software features, and amplifier features, the NeuroField Q21 is substantially equivalent to the predicate device, the Cadwell Apollo System (K201819), and has spatial and temporal sampling substantially equivalent to the secondary predicate device, the NeuralScan System by Medeia, Inc. (K192753).

The comparison between the NeuroField Q21 and the predicate Cadwell Apollo System (K201819) below consists of a series of tables followed by explanations of the similarities and differences described in each table. A secondary predicate device, the NeuralScan System by Medeia, Inc. (K192753) is used in the subsequent discussion of spatial and temporal sampling.

I. Comparison of Regulatory Parameters

Comparison	Neurofield Q21	Cadwell Apollo System (K201819)
Indications for use	The NeuroField Q21 System is indicated for prescription use to acquire, record, transmit, and display physiological data for electroencephalographic (EEG) studies of patients of all ages.	The Cadwell Apollo System is indicated for prescription use to acquire, record, transmit, and display physiological and **environmental** data for electroencephalographic (EEG) **and polysomnographic (PSG) ambulatory and/or clinical** studies of patients of all ages.

Intended population	Patients of all ages.	Patients of all ages.
Common or usual name	EEG	EEG
Regulatory Class	Class II	Class II
Classification name and product code	882.1400 Electroenceph-alograph GWQ	882.1400 Electroenceph-alograph GWQ

Discussion of Similarities and Differences

The two systems are materially the same in most regulatory parameters:

- Both are an electroencephalograph that can be used with all ages of patients
- Both are for prescription use in EEG studies
- Both can acquire, record, transmit, and display physiological data
- Both have the same classification name, product code, and regulatory class

The two systems differ slightly in their indications for use:

- The Cadwell Apollo System has indications for use for "**polysomnographic (PSG) ambulatory and/or clinical"** studies and "**environmental data**", whereas the Q21 does not. The Q21 therefore makes fewer claims than the predicate, but this does not affect the ability of either to perform as an electroencephalograph.

II. Comparison of Features – Software

Comparison	Neurofield Q21	Cadwell Apollo System (K201819)
Realtime EEG recording and viewing	Yes	Yes
Adjustable vertical and horizontal display scale	Yes	Yes
Adjustable highpass, lowpass, and notch filter	Yes	Yes
File import and offline review	Yes	Yes
File export and sharing	Yes (EDF (European Data Format) and XDF (Extensible Data Format) file formats)	Yes (EDF (European Data Format))
Show/Hide individual channels	Yes	Yes
Remontaging	Yes	Yes
Ability to add event markers	Yes	Yes
Video recording	No	Yes

Discussion of Similarities and Differences

The two systems are substantially equivalent with respect to the implementation of most standard EEG software features, including:

- Realtime EEG recording and viewing
- Adjustable vertical and horizontal display scale
- Adjustable highpass, lowpass, and notch filter
- File import and offline review
- File export and sharing
- Show/Hide individual channels
- Remontaging
- Ability to add event markers

The two systems differ with respect to video recording:

- The Cadwell Apollo System can record video synchronized with the EEG, whereas the Q21 cannot. Given the lack of Q21 claims with respect to polysomnographic (PSG) studies, this lack of video recording is not detrimental to the intended use, whereas video EEG is a necessary feature for the predicate to allow it to perform PSG studies.

III. Comparison of Features – Hardware

Comparison	Cadwell Apollo System (predicate K201819)	Neurofield Q21
Maximum number of channels	32	20
Individual electrode support	Yes	Yes
Electrocap support	Yes	Yes
Input dynamic range	> ± 300 mV	± 375 mV
A/D resolution	16 bit	24 bit
Sampling rate	Up to 2300 Hz	256 Hz
Notch filter	50 Hz and 60 Hz	50 Hz and 60 Hz
Input impedance	20 GΩ	>1000GΩ
Common Mode Rejection Ratio (CMRR)	>110dB	>110dB
Noise level	<2 μV	1 μV
Patient isolation type	Isolation transformer	optical
Isolation voltage	>2500 V	>2500 V
Digital interface	Ethernet	CANBus
Power supply	Li-Ion Battery	Li-Ion Battery

Discussion of Similarities and Differences

The hardware for the two systems has many similar features, including:

- Support for the standard Electrocap electrode system
- Notch filtering at 50 and 60 Hz to reduce mains (line) noise
- High input impedance
- High common mode rejection ratio
- Input dynamic range that meets or exceeds IEC 80601-2-26:2019
- Patient isolation exceeding 2500 V
- A digital interface
- Battery power using Li-Ion

The spatial and temporal sampling of the two systems differ in that the predicate samples 32 locations at up to 2300 Hz, whereas the Q21 device samples 20 locations at 256 Hz. By considering a secondary predicate EEG device, the NeuralScan System by Medeia, Inc. (K192753), it's made apparent that 20 locations and 256 Hz is still common for traditional EEG systems:

Comparison	Medeia, Inc. NeuralScan System (secondary predicate K192753)	Neurofield Q21
Maximum number of channels	Up to 21	20
Sampling rate	200, 500, 1000 Hz	256 Hz

That secondary predicate device is itself favorably compared (in K192753) to systems with *maximum* temporal sampling of 250 Hz, and *maximum* spatial sampling of 19 and 7 channels. Consequently, the 20 channels and 256 Hz sampling of the Q21 is substantially equivalent to the spatial and temporal sampling of the secondary predicate device and other contemporary EEG systems.

The Q21 and predicate hardware differs in a few other ways:

- The Q21 hardware has a better A/D conversion depth (24 bits) than the predicate device (16 bits).
- The Q21 hardware has a better input impedance (1000 GΩ) than the predicate device (20 GΩ).
- The Q21 hardware has optical patient isolation, whereas the predicate device uses an isolation transformer.
- The Q21 hardware uses CANbus for digital communication, whereas the predicate device uses Ethernet.

IV. Comparative Performance Evaluations

Comparative performance evaluations are not necessary to demonstrate substantial equivalence to the predicate device.

V. Clinical Performance Evaluations

Clinical performance evaluations are not necessary to demonstrate substantial equivalence to the predicate device.

VI. Non-Clinical Performance Evaluations

The Q21 device was tested and meets the requirements of the following external standards:

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)
- IEC 60601-1-2:2014+A1:2020
- IEC 80601-2-26:2019

In addition, software verification and validation testing were conducted following FDA guidance for software contained in medical devices. The software was determined to be "moderate" level of concern since a failure or latent flaw could indirectly result in a minor injury to the patient through incorrect or delayed information or through action of the operator.

VII. Conclusion

The two devices have the same intended use and the same main classification. They have many of the same features. They are used on the same populations. The two products are different in minor ways that do not materially affect their technological basis or use.

Based upon comparisons of regulatory parameters, software features, and amplifier features, the NeuroField Q21 is substantially equivalent to the predicate device, the Cadwell Apollo System (K201819), and has spatial and temporal sampling substantially equivalent to the secondary predicate device, the NeuralScan System by Medeia, Inc. (K192753).