April 27, 2023

Cumulus Neuroscience Limited
% Patsy Trisler
Regulatory Consultant
QServe Group, US, Inc.
7949 Beaumont Green East Drive
Indianapolis, Indiana 46250

Re: K221963
Trade/Device Name: Cumulus Functional Neurophysiology Platform
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ
Dated: March 24, 2023
Received: March 27, 2023

Dear Patsy Trisler:

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

Patrick Antkowiak
Acting 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)*
K221963

Device Name

Cumulus Functional Neurophysiology Platform

Indications for Use *(Describe)*

The Cumulus Functional Neurophysiology Platform is intended for the acquisition, display and storage of electroencephalograph (EEG) obtained by placing electrodes on the head of adults and adolescent patients. The EEG signals are time-stamped.

The system can be used in the patient's home or a health care facility.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary – K221963

I. SUBMITTER	
Submitter Name:	Cumulus Neuroscience Limited
Submitter Address:	Cumulus Neuroscience Limited Concourse Building 3 Queens Road Belfast BT3 9DT Northern Ireland, United Kingdom
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Telephone:	+44 (0)28 9264 6600
Date Prepared:	27 April 2023

II. DEVICE	
Trade Name:	Cumulus Functional Neurophysiology Platform
Common Name	Electroencephalograph
Regulatory Name **Classification** **Product Code**	Full-montage standard EEG 882.1400 GWQ

III. PREDICATE DEVICE	
Primary Predicate	K192753, NeuralScan System, Medeia, Inc.

IV. INDICATIONS FOR USE STATEMENT

The Cumulus Functional Neurophysiology Platform is intended for the acquisition, display, and storage of electroencephalograph (EEG) obtained by placing electrodes on the head of adults and adolescent patients. The EEG signals are time-stamped. The system can be used in the patient's home or a health care facility.

V. DEVICE DESCRIPTION

Device Identification: **Components**	The Cumulus Functional Neurophysiology Platform is comprised of the Cumulus Headset which records EEG signals that are time-stamped.
and **Technological Characteristics**	The Cumulus software application runs on a mobile device running android software. The software has graphical user interface that provides guidance to the user to place the headset correctly. The EEG data is received from the headset via Bluetooth. The data received is synchronised and timestamped between the headset and app.

	The Cumulus Medical Device Hub provides the user interface for health care professionals to view, download and review data from the recordings.
	
	The Platform components are:
	• Cumulus EEG Headset with embedded software, which includes:
	  • An adjustable shell into which 16 Ag/AgCl EEG conductive sensors are attached.
	  • A zippered pocket for holding the detachable electronics.
	  • Interface buttons, LEDs, micro USB socket.
	• Plastic-encased 'Puck' electronics.
	• Cumulus Mobile device with installed Cumulus Mobile App.
	• Disposable mastoid sticky sensors
	• Earphones
	• Device stand
	• Headset and mobile device chargers
	
	Patient contacting materials are biocompatible, commercially sourced and are used in the headset without modifications.
	
	The device and accessories are not sterile, nor intended to be sterilized.

VI PERFORMANCE AND SAFETY TESTING

Animal Testing:	This product category does not require animal testing.
Clinical Testing:	This product category does not require animal testing.
Non-Clinical Testing:	Bench testing was conducted on the following and study reports were submitted in the 510(k): • Electrical safety • Electromagnetic compatibility • Hardware verification • Software verification and validation testing • Biocompatibility verification • Human Factors validation • Mechanical wear and durability of electrodes • Electrochemical characterization • Wireless Coexistence Testing The Cumulus Functional Neurophysiology Platform meets the requirements of the following international standards: • DIN EN ISO 10993-1:2018: *Biological Evaluation of Medical Devices, Part 1: Evaluation and testing within a risk management system.* • DIN EN ISO 10993-5:2009: *Biological Evaluation of Medical Devices, Part 5: In vitro cytotoxicity* • ISO 10993-10:2021: *Biological evaluation of medical devices - Part 10: Tests for skin sensitization* • ISO 10993-12:2021: *Biological evaluation of medical devices - Part 12: Sample preparation and reference materials*

	• ISO 10993-23:2021: Biological evaluation of medical devices - Part 23: Tests for irritation • IEC 60601-1:2005+AMD1:2012 (ed 3.1) Medical Electrical Equipment - Part 1: *General requirements for basic safety and essential performance.* • IEC 60601-1-2:2015 *Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.* • IEC 60601-1-11:2015 *Medical Electrical Equipment - Part 1-11: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.* • IEC 80601-2-26:2019 *Medical Electrical Equipment Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs.* • ANSI C63.10 2013 *American National Standard of Procedures for Compliance Testing of Unlicensed Wireless Devices* • ANSI 63.4 2014 *American National Standard for Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz* • IEC 62304 Edition 1.1 2015 -06 Consolidated Version *Medical device software – Software life cycle processes* • ISTA 3A 2018 *Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less*
Biocompatibility Testing:	A biocompatibility evaluation was conducted according to ISO 10993-1. It concluded testing was required to assure the intact skin contact components for the prolonged (cumulative) use are biocompatible and non-toxic. Reports presenting the cytotoxicity testing (according to ISO 10993-5) and evaluation of extractable metallic ions and organic compounds (according to ISO 10993-18) of the Ag/AgCl skin contacting sensors were presented in the 510(k). Additional testing for delayed hypersensitivity (according to ISO 10993-10) and intracutaneous reactivity (according to ISO 10993-23) was completed. Testing was conducted by a third party according to Good Laboratory Practices. Results showed the subject device is biocompatible and non-toxic for its intended use.

VII SUBSTANTIAL EQUIVALENCE COMPARISON TABLE

	NEW DEVICE	PRIMARY PREDICATE	Comparison
510(k) #	K221963	K192753	N/A
DEVICE NAME	Cumulus Functional Neurophysiology Platform	NeuralScan System	
MANUFACTURER	Cumulus Neuroscience Ltd	Medeia, Inc.	
PRODUCT CODES: PRIMARY	GWQ	OLT, GWJ, GWQ	Same

REGULATORY NAME: **CLASSIFICATION:** **CLASS:**	Electroencephalograph 21 CFR 882.1400 II	Electroencephalograph 21 CFR 882.1400 II	
INDICATIONS FOR USE	The Cumulus Functional Neurophysiology Platform is intended for the acquisition, display and storage of electroencephalograph (EEG) obtained by placing electrodes on the head of adults and adolescent patients to aid in diagnosis. The EEG signals are time-stamped. The system can be used in the patient's home or a health care facility.	The NeuralScan System is intended for the acquisition, display, analysis, and storage, of electrical activity of a patient's brain including electroencephalograph (EEG) and Event-related Potentials (ERP), obtained by placing two or more electrodes on the head to aid in diagnosis.	Same intended use. SE for Indications
Rx Only or OTC	Rx Only	Rx Only	Same
PRINCIPLE OF OPERATION and SYSTEM COMPONENTS	Used for acquisition of physiological signals using 2 or more channels of EEG from the scalp. It consists of a mobile device with mobile app software, a patient EEG Headset, earphones, and charging cord for EEG Headset and mobile device . The technology provides a means to: • Initiate a study, track user EEG data • Acquire and save signals to memory of the device, • Transmit signal data from device, • Visually inspect acquired signal,	Used for acquisition of physiological signals using 2 or more channels of EEG from the scalp. It consists of an amplifier and software, a laptop computer (base station), a patient EEG cap, response button, ear buds and charging cord. The technology provides a means to: • Initiate a study, track user EEG and ERP data and enter text or questionnaire information • Acquire and save signals to memory of the device, • Transmit signal data from device, • Visually inspect acquired signal, • Manage ERPs.	SE
PATIENT POPULATION	Adolescents and adults	All age groups	SE
USE ENVIRONMENT	Healthcare and medical facilities, athletic and sports clinics, or outside facilities if led by qualified medical personnel. In addition, it may be used in the home.	Healthcare and medical facilities, athletic and sports clinics, or outside facilities if led by qualified medical personnel	SE
BIOCOMPATIBILITY	Per ISO 10993-1	Per ISO 10993-1	Same
STERILE	No	No	Same
SINGLE USE	No	No	Same
SHELF LIFE	Durable goods	Durable goods	Same
POWER	Li-Ion Battery, with USB cable for charging battery	Li-Ion Battery, with USB cable for charging battery	
Rx Use or OTC	Rx Use	Rx Use	Same

System Components	• Patient EEG Headset • Mobile device with mobile app software • Earphones • Web dashboard software • Charging cords for EEG cap and mobile device	• Patient EEG cap • NeuralScan amplifier • Laptop computer • Subject Response button • Ear buds • Charging cord	
Interface	Bluetooth (EEG to mobile device) and WiFi (mobile device to cloud)	USB or WiFi to laptop	SE
Biopotential signals recorded	Electroencephalography (EEG),	Electroencephalography (EEG), EP/ERP	Same
Electroencephalography (EGG)			
Skin Coupling	Dry electrodes	Custom Electrode Band and Gel	SE
Signal recording channels	16	Up to 23	SE
EEG input terminals	16	Up to 21	SE
Analog to Digital Conversion	24 bits	24 bits	Same
Sampling Rate	250 and 500 Hz	200, 500, 1000 Hz	SE
Common Mode Rejection	>110 dB	>110 dB	Same
Analysis Software	Embedded and user defined.	Embedded, commercially available, and user defined.	SE
Resolution	24 bits	24 bits	Same
Band Pass	0.5 – 50 Hz	0.1 – 50 Hz	SE
Noise	1.6 µVp-p	2.3 µVp-p	SE
Input Voltage range	+/- 200 mV	+/- 400 mV	SE

VIII COMPARISON TO THE PREDICATE DEVICE OF TECHNOLOGICAL CHARACTERISTICS

As shown in the Substantial Equivalence Comparison Table, the intended use, principle of operation and system components, method of contact, user interface, and software design of the Cumulus Functional Neurophysiology Platform compared to the NeuralScan System Primary Predicate are similar.

While the software components of subject device and Predicate are proprietary and thus different, each is evaluated according to FDA's software verification and validation processes. In addition, the specific design of the Cumulus headset is different from the Predicate, however, the recording methodologies used are common in clinical research and typically delivered using lab-suitable technologies (e.g. a PC and computer screen). The Cumulus system uses a mobile device to increase convenience of use and ease of deployment and provides a controlled platform with well-understood technical characteristics.

The differences, in comparison to the Predicate device, raise no new questions of safety and effectiveness.

VIX CONCLUSION

Based on the comparisons shown in Substantial Equivalence Comparison table, the Cumulus Functional Neurophysiology Platform device is substantially equivalent to the Predicate NeuralScan System. The nonclinical data support the safety of the device system and the hardware and software verification and validation demonstrate that the subject device should perform as intended in the indicated environments.