June 16, 2022

Seer Medical Pty. Ltd.
David Mitchell
Quality and Regulatory Manager
278 Queensberry Street,
Melbourne 3000, Victoria, Australia

Re: K212788
Trade/Device Name: Seer Home
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ
Dated: July 28, 2021
Received: September 1, 2021

Dear David Mitchell:

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,

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)*
K212788

Device Name
Seer Home

Indications for Use *(Describe)*
The electroencephalographic system Seer Home is intended to acquire, display, and store the electro-physiological signals of the patient's brain obtained by placing electrodes on the patient scalp.

The Seer Home is intended to be used for such studies as electroencephalograph (EEG) and video EEG recording to aid in diagnosis of neurological disorders. The Seer Home does not draw any diagnostic conclusions.

Seer Home is not intended for use as life support equipment such as vital signs monitoring in intensive care units.

Seer Home is only to be used under the direction and supervision of a physician or EEG technologist or clinician.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

The following 510(k) summary is being submitted in accordance with 21 CFR 807.92

Device Information:

Submitter:	Seer Medical Pty. Ltd.
Address:	278 Queensberry Street, Melbourne 3000, Victoria, Australia Tel: +61 (0) 3 7035 5736
Contact Person	David Mitchell – Quality and Regulatory Manager Tel: +61 (0) 3 7035 5736 Email: david@seermedical.com
Date prepared:	28th July 2021
Trade or Proprietary Name:	Seer Home
Device Type:	Full-Montage Standard Electroencephalograph
Product Code:	GWQ
Device Class:	II
Regulation numbers:	21 CFR 882.1400
Regulation description:	Electroencephalograph

Legally Marketed Predicate Device Information:

Trade or Proprietary Name:	ElectroTek (Trackit EEG hardware & RENDR software)
Manufacturer Name:	MobileMedTek 1205 E. Washington St., Suite 115 Louisville, KY 40206
Device Type:	Full-Montage Standard Electroencephalograph
510(k) Number:	K170441
Product Code:	GWQ
Device Class:	II
Regulation numbers:	21 CFR 882.1400
Regulation description:	Electroencephalograph

Device Description:

The Seer Medical - Seer Home is an ambulatory electroencephalograph system designed to be used at the patient's home for up to week-long studies. The ambulatory EEG recorder (called "Seer Sense" or "Wearable") is worn around the patient shoulders. The Wearable has a single cable exiting from the bottom of the device and is routed inline to 3 disposable ECG electrodes which are positioned on the chest for ECG recording. Exiting from the rear of the Wearable is single flexible cable which has a junction at the top of the patient's head connected to the 22 EEG electrodes (disposable) which are positioned in the international '10-20' system for EEG recording.

The Wearable records the EEG and ECG signals and wirelessly transmits them to a nearby "Seer Sight Video Monitoring Hub" in the patient's house. The Video Monitoring Hub has two roles, first to store the wireless data from the wearable, and the second is to record video from an in-built camera that is synchronized to the EEG/ECG data. The use of the recorded video data provides additional information to the physician (such as body movement artifacts) to assist in diagnosis in the neurological conditions.

At the end of the study period (up to a week) the Wearable and Hub are returned back to the clinic for data download. The Seer Cloud Platform software downloads the data, stores the data, displays the EEG/ECG signals and video for reviewers to interpret, make annotations, and produce reports.

The Seer Home is intended to be used by qualified operators or physicians trained in the interpretation of EEG/ECG signals and visual cues of patient movements - and is viewed as a part of a range of assessments used by Neurologists to assist in making diagnosis of neurological conditions.

The accessories used with the Seer Home are disposable EEG electrodes, disposable ECG electrodes, Transport/Carry case, Medical Grade Power Adapter, IFU, and Rechargeable Batteries.

Indications for Use:

The electroencephalographic system Seer Home is intended to acquire, display, and store the electro-physiological signals of the patient's brain obtained by placing electrodes on the patient scalp.

The Seer Home is intended to be used for such studies as electroencephalograph (EEG) and video EEG recording to aid in diagnosis of neurological disorders. The Seer Home does not draw any diagnostic conclusions.

Seer Home is not intended for use as life support equipment such as vital signs monitoring in intensive care units.

Seer Home is only to be used under the direction and supervision of a physician or EEG technologist or clinician.

Technological Characteristics:

The Seer Home is an ambulatory electroencephalograph system and has similar indication for use statement as the predicate device. The Seer Home also has similar technological characteristic as the predicate device.

Listed on Table 1. Is a summarized version of the technological comparison between the Seer Home and predicate device. The table has same format and data as the predicate device K170441 510(k) Summary, with the addition of a comparison column.

Table 1:
Summary of the technological characteristics of the device compared to the predicate device

Characteristics	Subject Device: Seer Medical *Seer Home™* (K212788)	Predicate Device MobileMedTek *ElectroTek* (K170441)	Similarities, differences, impact
1. Indication			
1.1 INDICATIONS FOR USE	The electroencephalographic system Seer Home is intended to acquire, display, and store the electro-physiological signals of the patient's brain obtained by placing electrodes on the patient scalp. The Seer Home is intended to be used for such studies as electroencephalograph (EEG) and video EEG recording to aid in diagnosis of neurological disorders. The Seer Home does not draw any diagnostic conclusions. Seer Home is not intended for use as life support equipment such as vital signs monitoring in intensive care units. Seer Home is only to be used under the direction and supervision of a physician or EEG technologist or clinician.	The electroencephalographic system ElectroTek is intended to acquire, display, and store the electrical activity of a patient's brain obtained by placing electrodes on the patient scalp. The ElectroTek is intended to be used for such studies as electroencephalogram (EEG) and video EEG recording to aid in diagnosis. The ElectroTek does not draw any diagnostic conclusions.	Same. Both systems are indicated for Video EEG studies with similar intended use which do not draw any diagnostic conclusions.
1.2 WARNINGS	Items related to off-label use or misuse	Items related to off-label use or misuse	Same. Standard warnings for EEG device.
1.3 CONTRAINDICATIONS	Items related to design and indicated use limitations, such as, not for use in the presence of flammable anesthetic's or in conjunction with defibrillation or electro-surgical equipment.	Items related to design and indicated use limitations, such as, not for use in the presence of flammable anesthetic's or in conjunction with defibrillation equipment.	Same. Not be used in the presence of flammable gases, defibrillation equipment or electro-surgical equipment stated in IFU and labelling.
1.4 Clinical Indications for Use	Assisting in the diagnosis of neurological disorders.	Assisting in the diagnosis of neurological disorders.	Same. Both systems are used for assisting in the diagnosis of neurological disorders.
1.5 Intended Patient Population	Patients requiring monitoring of their physiological signals to assist in diagnosis.	Patients requiring monitoring of their physiological signals to assist in diagnosis.	Same intended patient population.
1.6 Intended Users	For use by neurological and other related healthcare professionals.	For use by neurological and other related healthcare professionals.	Same intended users.
1.7 Environment of Use	For use in either a home or hospital/clinic environment. The Seer Home is not for use in intensive care or other life support situations.	For use in a either a home, hospital/clinic environment. The ElectroTek is not for use in intensive care or other life support situations.	Same environment of use.
1.8 Components of the System	• Seer Sense wearable. • Monitoring Hub. • Seer Cloud Platform software.	• ElectroTek – Trackit Amplifier • Trackit F (Laptop, Camera, and Case) • RENDR EEG software.	Same. The Seer wearable performs the same function as the Trackit amplifier, the Monitoring Hub the same as the Trackit F Laptop/Camera, and the

Characteristics	Subject Device: Seer Medical *Seer Home™* (K212788)	Predicate Device MobileMedTek *ElectroTek* (K170441)	Similarities, differences, impact
			Seer Cloud Platform software performs the same functions as the RENDR EEG software.
1.9 Duration/application of use	Normal use is up to a week.	Usage depends on battery life which is 72 hours for the battery pack.	Same. Both devices are used for longer term home usage (> 24 hours). Seer Home has longer duration of use primarily driven by longer battery life.
1.10 Portable / ambulatory	Yes	Yes	Same. Both devices are portable / ambulatory.
2. Technical - Overview			
2.1 GENERAL SYSTEMS APPROACH	Computer based equipment with dedicated hardware peripherals / Components	Computer based equipment with dedicated hardware peripherals / components	Same. Display and Analysis software operates on standard computer hardware. Acquisition is performed on dedicated medical hardware.
2.2 USER INPUT DEVICE	Window mouse / keyboard / graphic interface. Simple user interface.	Window mouse / keyboard / touch panel driven graphic interface with dedicated control panel	Same. Display and Analysis software operates on standard computer hardware using GUI/keyboard/mouse. Different: The Amplifier UI interface is slightly different having a color-coded LEDs instead of LCD, this difference is minor and is assessed in the Usability assessment and found not to affect safety and effectiveness.
2.3 USER OUTPUT DEVICE	Digital color display and optional network printer connectivity	Digital color display and optional network printer connectivity	Same. Display and Analysis software operates on standard computer hardware.
2.4 PATIENT INPUTS	Up to 22 channels EEG and 2 channels ECG	Up to 32 channels EEG/EMG	Same. Both systems allow complete 10-20 positioning of scalp electrodes. Different. Additional electrodes for other electro-physiological inputs – ECG inputs for the Seer Home and EMG for ElectroTek. The additional inputs do not affect safety or performance for product code GWQ or impact the indications for use.
2.5 SIGNAL ACQUISITION	Analog to digital conversion at fixed sample rate	Analog to digital conversion at variable sample rate	Different. Maximum sampling rates are the same: 500Hz. Predicate allows for selection of other lower frequency fixed rates. The sampling rate of 500 Hz is a requirement for compliance to the international EEG standard, so the difference does not affect safety or performance.
2.6 TRIGGER INPUT	Yes	Yes	Same. Trigger input for patient event recording.

Characteristics	Subject Device: Seer Medical *Seer Home*™ (K212788)	Predicate Device MobileMedTek *ElectroTek* (K170441)	Similarities, differences, impact
2.7 TRIGGER OUTPUT	No	Yes	Different. No external interface to third party devices. This does not affect intended use, or safety of effectiveness.
2.8 USE OF STANDARD SOFTWARE PLATFORM (Operating System)	Yes, Microsoft Windows Platform: SEER CLOUD display and analysis software	Yes, Microsoft Windows: RENDR display and analysis software	Same. Display and analysis software operate on same operating system and perform similar functions
2.9 CUSTOMIZATION OF PROTOCOLS	Via storage / retrieval of user defined settings	Via storage / retrieval of user defined settings	Same. Display and analysis software perform similar function and user configuration settings
2.10 APPLICATION FLEXIBILITY / EXPANDABILITY	Via SEER CLOUD software update	Via RENDR software update	Same. Display and analysis software updated via cloud platform
2.11 SAFETY STANDARDS	IEC 60601-1 ed3.1, IEC 60601-1-2 ed4.0, IEC 60601-1-11 ed2.0 IEC 60601-2-26 ed3.0, IEC 60601-2-25 ed2.0, ISO 10993-1 ed5.0 2018	IEC 60601-1 ed3.1, IEC 60601-1-2 ed3.0, IEC 60601-2-26 ed3.0, IEC 60601-2-40:1998, ISO 10993-1:2009	Same. Primary Standards - Safety, EMC, EEG, and Biocompatibility. Difference. Seer Home has additional compliance with (1-11) Medical Home Usage standard, and (2-25) ECG. ElectroTek has additional compliance with (2-40) EMG. The additional compliance, and not having compliance to (2-40) EMG does not affect safety or performance for product code GWQ or impact the indications for use.
2.12 PATIENT CIRCUITRY ISOLATION	Transformer and wireless comms isolation	Transformer	Same. Electrical Isolation is provided by transformer isolation and wireless comms for the wearable that is isolated from the mains by an internal battery.
2.13 SYSTEM COMPONENTS	Wearable EEG internal amplifier & recorder including trigger input, Wireless comms. Portable Hub computer, Wireless comms, and USB video camera.	Base console including trigger input/output, LED interface/photic stimulator; Control panel; internal amplifier; laptop computer with integrated display, USB video camera, keyboard and trackpad.	Same. Key components of the system are the same: EEG amplifier, acquisition computer system and video camera.
2.14 SYSTEM - COMPUTER INTERFACE	Ethernet	USB	Same. Wired digital communication link. Ethernet being faster and having transformer isolation.
2.15 SYSTEM POWER SUPPLY	Mains (100-240 VAC) thru an isolated power supply	Mains (100-240 VAC) thru an internal isolated power supply	Same. Certified isolated mains power supply.
2.16 AMPLIFIER POWER SUPPLY	3.7 VDC from internal battery	+/- 3 VDC from base console	Same. Low voltage powered EEG amplifiers; both are battery powered.
2.17 SIZE (L/W/D) cm	22 x 22 x 7 cm Amplifier 84 x 36 x 23 cm (Hub unit - case)	14 x 9.5 x 3 cm Amplifier 53.10 x 26.95 x 4.45 cm (base console + laptop)	Same. Similar form-factor: a wearable Amplifier and portable acquisition

Characteristics	Subject Device: Seer Medical *Seer Home*™ (K212788)	Predicate Device MobileMedTek *ElectroTek* (K170441)	Similarities, differences, impact
		56 x 36 x 23 cm (Trackit F - case)	computer, housed in pelican case for transport.
2.18 WEIGHT kg	225 g (amplifier) 15 kg (hub)	575 g (amplifier) 3.987 kg (base console)	Different. Predicate acquisition computer weighs less than Seer Home Hub, but conversely wearable predicate amplifier weighs more than Seer Home. The usability study considers the weight of the wearable and hub on patient study and were found not affect intended use, safety of effectiveness.
3. Technical – EEG			
3.1 NUMBER OF CHANNELS	Up to 24 channels	Up to 32 channels	Same. Both systems allow 10-20 electrode placement to perform EEG study. Different. After allocation of channels to 10-20 placement the predicate will have unused spare channels for additional inputs. Seer Home not having spare channels will not affect safety or performance for product code GWQ or impact the indications for use.
3.2 CMRR Common Mode Rejection Ratio	> 84 dB	> 110 dB	Same. Both systems meet CMRR requirement of the EEG standard > 80 dB
3.3 NOISE	< 6uV peak to peak (from 0.5 Hz to 60 Hz)	< 2.5uV peak to peak (from 0.5 Hz to 60 Hz)	Same. Both systems meet noise requirement of the EEG standard < 6 uVpp.
3.4 INPUT IMPEDANCE	> 100 MΩ	> 100 MΩ	Same. Both systems have high input impedance >100M.
3.5 LOW FILTER	0.5 Hz to 10 Hz	0.05 Hz to 39.8 Hz	Different. The low-end filter range is not defined by the international EEG standard. Both subject and predicate comply with the American Clinical Neurophysiology Society EEG filter guideline of 1 Hz. The difference in filter range does not affect safety and effectiveness.
3.6 HIGH FILTER	15 Hz to 70 Hz	1 Hz to 200 Hz	Different. The high-end filter range is not defined by the international EEG standard. Both subject and predicate comply with the American Clinical Neurophysiology Society EEG filter guideline of 70 Hz. The difference in filter range does not affect safety and effectiveness.
3.7 NOTCH FILTER	50 / 60 selectable	50 / 60 selectable	Same. Same mains notch filter selection frequencies.
3.8 A/D CONVERSION	24 bit	24 bit	Same. Same ADC resolution.

Characteristics	Subject Device: Seer Medical *Seer Home*™ (K212788)	Predicate Device MobileMedTek *ElectroTek* (K170441)	Similarities, differences, impact
3.9 SAMPLING RATE	500 Hz (EEG)	500 Hz (EEG)	Same. Sampling rate the same as determined by IEC standard.
3.10 TRIGGER MODE	Manual event marker	Manual event marker	Same. Manual event marker.

Further details of the technological characteristics that are similar with the predicate device are listed in the predicate comparison section provided in the device 510(k) submission.

Non-Clinical Performance Data:

The device development and verification have been carried out in accordance with FDA regulations for electroencephalographs 21 CFR 882.1400. The device was tested against recommended consensus standards for EEG's and applicable voluntary consensus standards.

Electrical Safety and EMC testing were performed, the system complies with the Medical Electrical Safety Standard IEC 60601-1, and the relevant device specific Part 2 standards IEC 60601-2-25 (ECG) and IEC 60601-2-26 (EEG). EMC Testing was also performed to the IEC 60601-1-2 standard for Electromagnetic Compatibility.

The biocompatibility evaluation for the Seer Home was conducted in accordance with the ISO 10993-1 standard for Biocompatibility, and applicable materials were tested to ISO 10993-5 for Cytotoxicity, and ISO 10993-10 for Sensitization & Irritation.

Software verification and validation testing were performed and documentation following the FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern, since a failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider. The software documentation is compliant with IEC 62304.

The usability evaluation for Seer Home was conducted in accordance with the FDA guidance document "Applying Human Factors and Usability Engineering to Medical Devices" February 3, 2016, and IEC 62366-1:2015 as recognized by FDA.

Device specific verification tests include package Drop testing to ASTM D5276, Input Impedance tests, Filter verifications, Home Use compliance to IEC 60601-1-11, and other verification tests not directly covered by the IEC 60601-1 such as event triggers, battery monitoring, audio and visual feedback tests.

The electrical, software, biocompatibility, and device testing results support that all specifications have met the acceptance criteria. The Seer Home has passed all the required testing. The tests support the claims of substantial equivalence and safe operation.

Clinical Performance Data:

There is no clinical testing required to support the medical device as the indications for use are equivalent to the predicate device. The clinical literature review performed, demonstrates that ambulatory electroencephalographs, including the predicate device have been on the market for many years with proven safety and efficacy for the indicated use. The verification testing of the device was found to be acceptable and supports the claims of substantial equivalence.

Conclusion:

Based on the technical evaluations, non-clinical and clinical performance data described above, the Seer Home™ has been demonstrated to be substantially equivalent as the predicate device - MobileMedTek ElectroTek (K170441) and raises no safety or effectiveness issues.