June 30, 2023

Epitel, Inc.
Randy Parry
Staff Regulatory Affairs Specialist
465 South 400 East, Suite 250
Salt Lake City, Utah 84111

Re: K230933
Trade/Device Name: REMI Remote EEG Monitoring System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMC, GXY
Dated: March 31, 2023
Received: April 3, 2023

Dear Randy Parry:

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)*
K230933

Device Name
REMI Remote EEG Monitoring System

Indications for Use *(Describe)*
The REMI Remote EEG Monitoring System is indicated for use in healthcare settings where near real-time and/or remote EEG is warranted and in ambulatory settings where remote EEG is warranted. REMI uses single use, single patient, disposable, wearable sensors intended to amplify, capture, and wirelessly transmit a single channel of electrical activity of the brain for a duration up to 30 days.

The REMI System uses the REMI-Mobile software application that runs on qualified portable general purpose computing platforms. REMI-Mobile displays user setup information to trained medical professionals and provides notifications to medical professionals and ambulatory users. REMI-Mobile receives and transmits data from connected REMI Sensors to the secure REMI-Cloud where it is stored and prepared for review on qualified EEG viewing software.

REMI does not make any diagnostic conclusion about the subject's condition and is intended as a physiological signal monitor. The REMI System is indicated for use with adult and pediatric patients (6+ years).

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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REMI Remote EEG Monitoring System
Traditional 510(k) Summary
K230933

1. Applicant Information

Epitel, Inc.
465 S 400 E Suite 250,
Salt Lake City, UT 84111

Primary Contact Information
Randy Parry
Staff Regulatory Affairs Specialist
Mobile: 801-497-6297
Email: r.parry@epitel.com

Secondary Contact Information
Christopher M. Phillips
VP, Regulatory Affairs and Quality
Mobile: 801-497-6297
Email: c.phillips@epitel.com

Date Prepared
June 30, 2023

2. Subject Device Information

Name of Device: REMI Remote EEG Monitoring System
Common or Usual Name: EEG System
Classification Name: Electroencephalograph,
Regulatory Class: Class II
Product Code and Regulation Number: OMC - Sec. 882.1400, GXY Sec. 882.1320

3. Predicate Device

Name of Device: REMI
510(k) Number: K203827
Manufacturer: Epitel, Inc

4. Device Description

REMI Sensors amplify electroencephalographic activity acquired from a patient's scalp. After amplification, the EEG data is sent to the REMI Mobile medical application running on a qualified commercial-off-the-shelf mobile computing platform. REMI Mobile combines the EEG from the REMI Sensors with corresponding patient information and relays the data to the REMI Cloud server. REMI Cloud processes the data into a format compatible for viewing using qualified EEG viewing software (initially qualified for viewing on Persyst 14 EEG Review and Analysis Software, K182181).

The REMI System has three major components:

1) REMI Sensor - A disposable EEG sensor which is placed on the patient's scalp using a conductive REMI Sticker
2) REMI Mobile – A mobile medical application that is designed to run on a qualified commercial-off-the-shelf mobile computing platform (an Android tablet for use in healthcare settings, and a portable/wearable Android smartwatch for use in ambulatory settings), acquire EEG data transmitted from REMI Sensors and then transmit the EEG data and associated patient information via wireless encrypted transmission to,
3) REMI Cloud – A HIPAA-compliant secure cloud storage and data processing platform where data is processed into a qualified EEG reviewing software format for neurological review.

This 510(k) submission includes the addition of the Android smartwatch for ambulatory use and increases the duration of monitoring to up to 30 days.

5. Intended Use

Acquisition and presentation of electroencephalographic (EEG) data.

6. Indications for Use

The REMI Remote EEG Monitoring System (REMI System) is indicated for use in healthcare settings where near real-time and/or remote EEG is warranted and in ambulatory settings where remote EEG is warranted. REMI uses single use, single patient, disposable, wearable sensors intended to amplify, capture, and wirelessly transmit a single channel of electrical activity of the brain for a duration of up to 30 days.

The REMI System uses the REMI Mobile software application that runs on qualified commercial off-the-shelf mobile computing platforms. REMI Mobile displays user setup information to trained medical professionals and provides notifications to medical professionals and ambulatory users. REMI Mobile receives and transmits data from connected REMI Sensors to the secure REMI Cloud where it is stored and prepared for review on qualified EEG viewing software.

REMI does not make any diagnostic conclusion about the subject's condition and is intended as a physiological signal monitor. The REMI System is indicated for use with adult and pediatric patients (6+ years).

7. Substantial Equivalence

The REMI System has been developed in compliance with applicable FDA requirements and guidance as well as with recognized standards. This submission includes required documentation and testing data demonstrating substantial equivalence of the REMI System to its predicate device. The device has undergone software testing, human factors/usability testing, electromagnetic compatibility and electrical safety testing, and biocompatibility testing, which demonstrate that it is safe and effective for its intended use. The subject REMI System presents no new significant risks or safety concerns, and any potential risks have been mitigated as low as reasonably possible.

7.1. Summary of Technological Characteristics and Substantial Equivalence

Attribute	Subject Device K230933 REMI Remote EEG Monitoring System	Predicate Device K203827 REMI
Intended Use	Acquisition and presentation of electroencephalographic (EEG) data.	Acquisition and presentation of electroencephalographic (EEG) data.
Indications for Use	The REMI Remote EEG Monitoring System is indicated for use in healthcare settings where near real-time and/or remote EEG is warranted and in ambulatory settings where remote EEG is warranted. REMI uses single use, single patient, disposable, wearable sensors intended to amplify, capture, and wirelessly transmit a single channel of electrical activity of the brain for a duration up to 30 days. The REMI System uses the REMI-Mobile software application that runs on qualified portable general purpose computing platforms. REMI-Mobile displays user setup information to trained medical professionals and provides notifications to medical professionals and ambulatory users. REMI-Mobile receives and transmits data from connected REMI Sensors to the secure REMI-Cloud where it is stored and prepared for review on qualified EEG viewing software. REMI does not make any diagnostic conclusion about the subject's condition and is intended as a physiological signal monitor. The REMI System is indicated for use with adult and pediatric patients (6+ years). (Rx only).	The REMI System is intended to be used in healthcare settings where near real-time and/or remote EEG is warranted. REMI uses disposable Sensors – a single use, single patient, disposable, wearable sensor intended to amplify, capture, and wirelessly transmit a single channel of electrical activity of the brain for up to 48 hours. The REMI Mobile software and REMI Tablet are intended to receive and transmit data from four REMI Sensors to secure cloud storage for subsequent viewing and reviewing of EEG on third-party software. REMI does not make any diagnosis or recommendations and is intended only as a physiological signal monitor. REMI Sensors are intended for use by trained medical professionals in a professional healthcare facility environment. REMI Sensors are intended for use with adult and pediatric patients (6+). (Rx only).
Use Environment	The REMI system is intended to be used in health care settings for near real time/and or remote EEG signal collection. The REMI system is intended to be used in ambulatory settings for remote EEG signal collection and includes home-use.	The REMI system is intended to be used in health care settings for near real time/and or remote EEG signal collection.
Software/System User Interface	REMI Mobile medical application The REMI Mobile application is run on qualified commercial off-the-shelf Android computing platforms.	REMI Mobile medical application The REMI Mobile application is run on qualified commercial off-the-shelf Android computing platforms.
Qualified Computing Platform Operating Systems	Android 11 or higher Wear OS 3.0 or higher	Android 6
Sensor User Interface	The REMI Sensor has a single push button integrated into the sensor that serves as the user interface. Some feedback about sensor status is given via an onboard LED.	The REMI Sensor has a single push button integrated into the sensor that serves as the user interface. Some feedback about sensor status is given via an onboard LED.
Physiological Signal Acquired	EEG acquired from a patient's scalp	EEG acquired from a patient's scalp

Attribute	Subject Device K230933 REMI Remote EEG Monitoring System	Predicate Device K203827 REMI
Patient Contact	REMI-Sticker accessory contacts the patient's skin (scalp).	REMI-Sticker accessory contacts the patient's skin (scalp).
Cumulative Wear Time	Up to 30 days. Prolonged contact.	Up to 48 hours. Prolonged contact.
Electrodes	2 passive gold electrodes that interface with the scalp through a conductive hydrogel integrated into the sticker.	2 passive gold electrodes that interface with the scalp through a conductive hydrogel integrated into the sticker.
Type of Use	REMI sensor is a non-sterile, single-use disposable device.	REMI sensor is a non-sterile, single-use disposable device.
Channels	Up to 10	Up to 10
Montage	10/20 system – REMI Sensor can be placed anywhere in the 10/20 system where each channel represents a bipolar derivation approximation of the 10/20 system	10/20 system – REMI Sensor can be placed anywhere in the 10/20 system where each channel represents a bipolar derivation approximation of the 10/20 system
Electrical Safety and EMC	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-26 IEC 60601-1-11:2015 /A1:2020	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-26
Input Range (sensors)	1 mVp-p	1 mVp-p
Input Noise (sensors)	5 μVp-p	5 μVp-p
Transfer of Data from the sensor to REMI Mobile (operating on a qualified computing platform)	Low power wireless personal area network	Low power wireless personal area network
Transfer of data from REMI Mobile to REMI Cloud	Secured WiFi or Cellular data connection	Secured WiFi or Cellular data connection
Power Source (sensors)	Primary lithium button cell (not rechargeable)	Primary lithium button cell (not rechargeable)
Data Format (Viewer software)	Common EEG data formats (e.g., lay-dat)	Common EEG data formats (e.g., lay-dat)
Firmware (sensors)	REMI sensors use integrated firmware to collect and transmit EEG data to the REMI Mobile application.	REMI sensors use integrated firmware to collect and transmit EEG data to the REMI Mobile application.
Software (REMI Cloud)	The REMI Cloud receives EEG data from the REMI Mobile app and prepares it into a format for viewing in the qualified EEG viewing software. REMI Cloud also facilitates transfer and subsequent receipt of EEG data for additional characterization by EEG analysis module(s).	The REMI Cloud receives EEG data from the REMI Mobile app and prepares it into a format for viewing in the qualified EEG viewing software.

Attribute	Subject Device K230933 REMI Remote EEG Monitoring System	Predicate Device K203827 REMI
Connector	REMI Sensors are equipped with a non-standard USB pinout/connector that is only used for programming during production. This interface is not used by the clinician or patient.	REMI Sensors are equipped with a non-standard USB pinout/connector that is only used for programming during production. This interface is not used by the clinician or patient.
Available Sizes (sensor)	REMI Sensor comes in one size: Width: 27 mm Length: 27 mm Depth: 7 mm	REMI Sensor comes in one size: Width: 27 mm Length: 27 mm Depth: 7 mm
Conductive Electrolyte Gel (sticker)	Conductive electrolyte is in the form of a hydrogel converted in a one-piece adhesive sticker as an accessory to the REMI Sensor. The sticker is replaceable and single use.	Conductive electrolyte is in the form of a hydrogel converted in a one-piece adhesive sticker as an accessory to the REMI Sensor. The sticker is replaceable and single use.
Biocompatibility	Biocompatibility of patient contacting components verified with Irritation, Sensitization, and Cytotoxicity testing per ISO 10993-5:2009 and ISO 10993-10:2010 for a prolonged time period.	Biocompatibility of patient contacting components verified with Irritation, Sensitization, and Cytotoxicity testing per ISO 10993-5:2009 and ISO 10993-10:2010 for a prolonged time period.

8. Performance Testing

Testing verifying the performance requirements of the subject device was conducted and is included in this premarket notification, the results of which support substantial equivalence. A summary of the testing is included below:

The REMI System was tested to verify its safe and effective use for the intended population and use environments. Testing included the following:

Test Type	Summary
General Electrical Safety, Electromagnetic Compatibility and Ingress Protection	Testing conducted to: IEC 60601-1:2005, including Amendment 2:2021, 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 60601-2-26:2015, Particular Requirements For The Basic Safety And Essential Performance Of Electroencephalographs IEC 60601-1-11:2015 + A1:2021, Medical Electrical Equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment

Test Type	Summary
Wireless Technology Testing	Wireless functionality is needed for the REMI System to achieve its Essential Performance. Because of this, comprehensive EMC testing of the REMI System has been conducted, including immunity to electromagnetic disturbance, in accordance with IEC 60601-1-2 and consistent with the requirements of IEC 60601-1-11. REMI Sensor wireless connectivity was tested with the qualified computing platform to demonstrate that wireless connections can be initiated, are stable, and are able to accurately transfer EEG signals. REMI Sensors were also tested to ensure that a wireless connection is able to be maintained for a minimum of 48 continuous hours.
Environmental/Shelf life	Accelerated aging and subsequent functional verification testing
Packaging Performance	Ship testing and subsequent functional verification testing
Biocompatibility	There are no new patient contacting components as part of this submission and no new biocompatibility testing was required. The patient contacting materials are identical to those presented in the predicate device submission (K203827). There have not been any changes to the material or tested contact type/duration.
Usability/ Human Factors	Human factors/usability testing was conducted to evaluate tasks associated with use of the device.
Software Testing	REMI Mobile software has been updated compared to the predicate software hand-off an initialized session from a primary computing platform (Android tablet) to a portable/wearable computing platform (Wear OS smartwatch) in order to support portable/wearable ambulatory use.
Bench Testing	End to end testing was conducted to ensure that the REMI System meets its Essential Performance: to record digitized EEG data with patient-applied sensors, and transfer the data, wirelessly, to a cloud-based archive. End to end testing verified that (1) the REMI System is able to acquire EEG signals using REMI Sensors and subsequently transmit that EEG data to REMI Mobile software, (2) that REMI Mobile is able to transfer the EEG data to the REMI Cloud, and (3) the final EEG file format within REMI Cloud is viewable in qualified EEG viewing software. This testing demonstrates that the REMI System meets its Essential Performance and fulfills system requirements.

The REMI Remote EEG Monitoring System met all predetermined acceptance criteria derived from the above listed tests and demonstrated substantially equivalent performance as compared with the predicate device.

9. Substantial Equivalence Conclusion

The subject device has the same intended use, similar indications for 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, REMI Remote EEG Monitoring System, is substantially equivalent to the identified predicate device.