May 21, 2025

Epitel, Inc.
Christopher Phillips
VP, Regulatory Affairs and Quality
465 S 400 E
Suite 250
Salt Lake City, Utah 84111

Re: K243185
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: February 21, 2025
Received: February 21, 2025

Dear Christopher Phillips:

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,

Jaime Raben -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.

Submission Number *(if known)*

K243185

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 System 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.

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 System does not make any diagnostic conclusion about the subject's condition and is intended as a physiological signal monitor. REMI System is indicated for use with adult and pediatric patients (1+ 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.

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

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REMI Remote EEG Monitoring System
Traditional 510(k) Summary

1. Applicant Information

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

Contact Information

Christopher M. Phillips
VP, Regulatory Affairs and Quality

Date Prepared

February 21, 2025

2. Subject Device Information

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

3. Predicate Devices

Predicate Type	510(k) Number	Name of Device	Name of Manufacturer
Primary Predicate	K230933	REMI Remote EEG Monitoring System	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 device (phone or 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 submission provides evidence to demonstrate that:

1. The REMI System is safe and effective for monitoring EEG of pediatric patients ages 1 through <6 years of age in all previously cleared use environments; and
2. A new/hydrocolloid REMI Sticker is safe and effective and is recommended for use with pediatric patients ages 1 through <6 years of age along with labeled instructions on daily skin-site checks.

5. 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 System 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.

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 System does not make any diagnostic conclusion about the subject's condition and is intended as a physiological signal monitor. REMI System is indicated for use with adult and pediatric patients (1+ years).

6. Predicate Selection

In alignment with FDA Draft Guidance *Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission - Draft Guidance for Industry and Food and Drug Administration Staff*, appropriate predicate devices have been selected. Potential predicates were reviewed and the REMI Remote EEG Monitoring System (K230933) was selected as it meets or exceeds the expected safety and performance, does not have unmitigated user-related or design related safety issues, and is not associated with any design-related recalls.

7. Substantial Equivalence

The REMI Remote EEG Monitoring 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 Remote EEG Monitoring System to its predicate device. The REMI Remote EEG Monitoring System has undergone Biocompatibility Testing and Clinical Assessment which demonstrate that it is safe and effective for its intended use. Assessment of the technological characteristics, intended use, and conclusions drawn from the verification tests, presented in their respective sections of this submission, demonstrate that the device is as safe and effective as the legally marketed predicate devices.

7.1. Summary of Technological Characteristics and Substantial Equivalence to Predicate Devices

Attribute	Subject Device REMI Remote EEG Monitoring System	Predicate Device REMI Remote EEG Monitoring System (K230933)
Classification and Regulation	Class II per 21 CFR 882.1400 Electroencephalograph (Head Set) Class II per 21 CFR 882.1320 (for electrodes within sensors)	Class II per 21 CFR 882.1400 Electroencephalograph (Head Set) Class II per 21 CFR 882.1320 (for electrodes within sensors)
FDA Product Code(s)	OMC - System GXY - Electrodes	OMC - System GXY - Electrodes
Intended Use	Acquisition and presentation of EEG data using wearable sensors	Acquisition and presentation of EEG data using wearable sensors
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 System 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. 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 System does not make any diagnostic conclusion about the subject's condition and is intended as a physiological signal monitor. REMI System is indicated for use with adult and pediatric patients (1+ years).	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).
Use Environment	The REMI System is indicated for use in health care settings for near real time and/or remote EEG signal collection. The REMI System is indicated for use in ambulatory settings for remote EEG signal collection.	The REMI System is indicated for use in health care settings for near real time and/or remote EEG signal collection. The REMI System is indicated for use in ambulatory settings for remote EEG signal collection.
Cumulative Wear Time	Up to 30 days. Prolonged contact.	Up to 30 days. Prolonged contact.
Software/System User Interface	REMI Mobile medical application The REMI Mobile application is run on qualified commercial off-the-shelf computing platforms.	REMI Mobile medical application The REMI Mobile application is run on qualified commercial off-the-shelf computing platforms.

Attribute	Subject Device REMI Remote EEG Monitoring System	Predicate Device REMI Remote EEG Monitoring System (K230933)
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
Patient Contact	REMI Sticker accessory contacts the patient's skin (scalp).	REMI Sticker accessory contacts the patient's skin (scalp).
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	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-26, IEC 60601-1-11
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 (proprietary Bluetooth)	Low power wireless personal area network (proprietary Bluetooth)
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)

Attribute	Subject Device REMI Remote EEG Monitoring System	Predicate Device REMI Remote EEG Monitoring System (K230933)
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). REMI Cloud includes an additional functionality that makes EEG data available to compatible module(s) for additional EEG data characterization.	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). REMI Cloud includes an additional functionality that makes EEG data available to compatible module(s) for additional EEG data characterization.
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 (sticker)	Biocompatibility of patient contacting components verified with Cytotoxicity, Sensitization, and Irritation for long-term use.	Biocompatibility of patient contacting components verified with Cytotoxicity, Sensitization, and Irritation for < 30 day use.

8. Performance Data

The REMI Remote EEG Monitoring System was tested to verify its design and to validate its safe and effective use for the intended population and use environments. Results of this testing, included in this premarket notification, support a determination of substantial equivalence. 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
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 operating REMI Mobile and with REMI Cloud to demonstrate that wireless connections can be initiated, are stable, and are able to accurately transfer EEG signals per FDA Guidance *Radio Frequency Wireless Technology in Medical Devices*. 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	Biocompatibility testing supporting long-term contact with intact skin was performed per ISO-10993-1 for all patient-contacting components that require premarket submission. Specific tests were completed according to ISO 10993-5, ISO 10993-10, and ISO 10993-23.
Usability/ Human Factors	Human factors/usability testing was conducted to evaluate tasks associated with use of the device.
Software Verification Testing	REMI Mobile software end-to-end testing has been 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 its predicate device.

9. Clinical Experience

Clinical experience provided in support of the subject device was gathered from NIH-funded

studies conducted by Epitel in support of REMI development efforts, conducted under Institutional Review Board oversight (and registered under NCT03583957). REMI Sensors experience at a single pediatric-focused site involved 318 pediatric patients with a mean REMI Sensor wear of 1.7 days across both healthcare facility and ambulatory settings (ages 1-21).

Retrospective review of pediatric REMI EEG records gathered from 13 younger pediatric patients (ages 1 to <6 years) enrolled at the site was completed. This review of REMI EEG data was performed by an experienced pediatric epileptologist independent of wired EEG and generally separated in time from the actual time of collection by over a year - to ensure appropriate experience, consistency, and minimization of bias. The review consisted of checks for quality of the resulting EEG records and assessments for EEG features. The review affirmed that each resulting REMI EEG record could potentially bring value to the clinical care of the young pediatric patients. Of note, the pediatric epileptologist identified three REMI EEG records where REMI Sensors had captured a seizure event.

This Clinical Experience with REMI Sensors and resulting REMI EEG records supports a conclusion that use of the REMI System (including wear of REMI Sensors and new/hydrocolloid REMI Stickers) is safe and effective for monitoring EEG of pediatric patients ages 1 through <6 years of age in all previously cleared use environments.

10. Substantial Equivalence Conclusion

The REMI Remote EEG Monitoring System 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, performance testing, and clinical experience to account for differences in technological characteristics as compared to the predicate, it can be concluded that the subject device, the REMI Remote EEG Monitoring System, is substantially equivalent to the identified predicate device.