



October 17, 2024

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

Re: K240408

Trade/Device Name: REMI-AI Rapid Detection Module (REMI-AI RDM)

Regulation Number: 21 CFR 882.1400

Regulation Name: Electroencephalograph

Regulatory Class: Class II

Product Code: OMB

Dated: September 16, 2024

Received: September 17, 2024

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not

required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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,

Jay R. Gupta -S

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

Indications for Use

Submission Number (if known)

K240408

Device Name

REMI-AI Rapid Detection Module (REMI-AI RDM)

Indications for Use (Describe)

The REMI-AI Rapid Detection Module (REMI-AI RDM) is a seizure detection module which is integrated into the REMI Remote EEG Monitoring System and is only indicated for use within non-ICU (Intensive Care Unit) healthcare settings. REMI-AI RDM has not been validated for and is not indicated for detection of electrographic status epilepticus.

REMI-AI RDM conducts automated analysis of REMI EEG data in near real-time and provides notifications of potential electrographic seizures (events) through the REMI System when seizure prevalence of 10% or greater (indicating seizure activity of at least 30 seconds within a 5-minute rolling window) is detected. When seizure prevalence is displayed, the notification also displays the corresponding event detection confidence. Notifications are intended to be used by qualified clinicians who will exercise professional judgment in their application. Detected events are also annotated in the associated REMI EEG record as an aide to the qualified physician's REMI EEG review.

Delays of up to several minutes may occur between the detection of an event and the generation of an event notification, and are thus not a substitute for real-time monitoring. REMI-AI RDM does not make any diagnostic conclusion about the subject's condition and is intended as a physiological signal monitor. REMI-AI RDM is indicated for use with adult and pediatric patients (6+ years).

Type of Use (select one or both as applicable)

Prescription Use (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-AI Rapid Detection Module (REMI-AI RDM) 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

October 9, 2024

2. Subject Device Information

Name of Device: REMI-AI Rapid Detection Module (REMI-AI RDM)

Common or Usual Name: EEG System

Classification Name: Automatic Event Detection Software For Full-Montage
Electroencephalograph

Regulatory Class: Class II

Product Code and Regulation Number: OMB - Sec. 882.1400

3. Predicate Devices

Predicate Type	510(k) Number	Name of Device	Name of Manufacturer
Primary Predicate	K191301	Ceribell Pocket EEG Device (Seizure Detection Module)	Ceribell, Inc.
Secondary Predicate	K231779	REMI-AI Discrete Detection Module (RDM)	Epitel, Inc.

4. Device Description

REMI-AI RDM conducts automated analysis of EEG data collected by the REMI System in near real-time. REMI-AI RDM provides notifications of the prevalence and confidence of potential electrographic seizures, having a combined prevalence of 10% or greater, which correlates with a duration of at least 30 seconds of activity within a rolling 5 minute window of EEG.

REMI-AI RDM notifications are presented through the REMI Mobile software application, and are intended to be used by qualified clinicians who will exercise professional judgment in their interpretation. Notifications include the prevalence and confidence value for the event and are marked in the associated EEG record in order to assist qualified clinicians in their assessment.

REMI-AI RDM notifications identify when a section of EEG is consistent with seizure characteristics it has been trained to recognize. When a notification is presented, clinical context and facility procedures should inform next steps in patient evaluation and management. REMI-AI RDM does not make any treatment or management recommendations.

Delays of up to several minutes may occur between the start of an event, the detection of an event and the generation of an event notification, and are thus not a substitute for real-time monitoring.

5. Indications for Use

The REMI-AI Rapid Detection Module (REMI-AI RDM) is a seizure detection module which is integrated into the REMI Remote EEG Monitoring System and is only indicated for use within non-ICU (Intensive Care Unit) healthcare settings. REMI-AI RDM has not been validated for and is not indicated for detection of electrographic status epilepticus.

REMI-AI RDM conducts automated analysis of REMI EEG data in near real-time and provides notifications of potential electrographic seizures (events) through the REMI System when seizure prevalence of 10% or greater (indicating seizure activity of at least 30 seconds within a 5-minute rolling window) is detected. When seizure prevalence is displayed, the notification also displays the corresponding event detection confidence. Notifications are intended to be used by qualified clinicians who will exercise professional judgment in their application. Detected events are also annotated in the associated REMI EEG record as an aide to the qualified physician's REMI EEG review.

Delays of up to several minutes may occur between the detection of an event and the generation of an event notification, and are thus not a substitute for real-time monitoring. REMI-AI RDM does not make any diagnostic conclusion about the subject's condition and is intended as a physiological signal monitor. REMI-AI RDM is indicated for use with adult and pediatric patients (6+ 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 Ceribell Pocket EEG Seizure Detection module primary predicate device 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. A secondary predicate was selected in the REMI-AI Discrete Detection Module as a secondary predicate in order to support some technological characteristics. The secondary predicate also 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

REMI-AI RDM 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 REMI-AI RDM to its predicate device. REMI-AI RDM has undergone Software Testing, Human Factors/Usability testing, and Clinical Validation 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-AI Rapid Detection Module	Primary Predicate Device Ceribell Pocket EEG Device (K191301)	Secondary Predicate Device REMI-AI Discrete Detection Module (K231779)
Classification and Regulation	Class II per 21 CFR 882.1400 Electroencephalograph	Class II per 21 CFR 882.1400 Electroencephalograph	Class II per 21 CFR 882.1400 Electroencephalograph
FDA Product Code(s)	OMB - Automatic Event Detection Software	OMB - Automatic Event Detection Software OMC - Reduced Montage System GWQ - Full Montage System GXY - Electrodes	OMB - Automatic Event Detection Software
Intended Use	Analysis of EEG signal data for detection of seizure events	Analysis of EEG signal data for detection of seizure events	Analysis of EEG signal data for detection of seizure events
Indications for Use	<p>The REMI-AI Rapid Detection Module (REMI-AI RDM) is a seizure detection module which is integrated into the REMI Remote EEG Monitoring System and is only indicated for use within non-ICU (Intensive Care Unit) healthcare settings. REMI-AI RDM has not been validated for and is not indicated for detection of electrographic status epilepticus.</p> <p>REMI-AI RDM conducts automated analysis of REMI EEG data in near real-time and provides notifications of potential electrographic seizures (events) through the REMI System when seizure prevalence of 10% or greater (indicating seizure activity of at least 30 seconds within a 5-minute rolling window) is detected. When seizure prevalence is displayed, the notification also displays the corresponding event detection confidence. Notifications are intended to be used by qualified clinicians who will exercise professional judgment in their application. Detected events are also annotated in the associated REMI EEG record as an aide to the qualified physician's REMI EEG review. Delays of up to several minutes may occur between the detection of an event and the generation of an event notification, and are thus not a substitute for real-time monitoring. REMI-AI RDM does not make any</p>	<p>The Ceribell Pocket EEG Device is intended to record and store EEG signals, and to present the EEG signals in visual and audible formats in real time. The visual and audible signals assist trained medical staff to make neurological diagnoses. The Pocket EEG Device is intended to be used in a professional healthcare facility environment.</p> <p>Additionally, the EEG Recording Viewer Software component of the Pocket EEG Device incorporates a Seizure Detection component that is intended to mark previously acquired sections of EEG recordings in patients greater than or equal to 18 years of age that may correspond to electrographic seizures in order to assist qualified clinical practitioners in the assessment of EEG traces. The Seizure Detection component provides notifications to the user when detected seizure prevalence is "Frequent," "Abundant," or "Continuous," per the definitions of the American Clinical Neurophysiology Society Guideline 14. Notifications include an on-screen display on the Pocket EEG Device and the optional sending of an e-mail message to a clinician. Delays of up to several minutes can occur between the beginning of a seizure and when the Seizure Detection notifications</p>	<p>The REMI-AI Discrete Detection Module (REMI-AI DDM) is indicated for the analysis of REMI Remote EEG Monitoring System electroencephalogram (EEG) recordings.</p> <p>REMI-AI DDM is intended to be used by physicians qualified to analyze and interpret EEG who will exercise professional judgment in using the information. As an aide to the qualified physician's REMI EEG review, REMI-AI DDM marks previously acquired sections of REMI EEG that may correspond to neurological events of interest indicative of potential electrographic seizures lasting at least 10 seconds in duration. REMI-AI DDM is indicated for use with adult and pediatric patients (6+ years).</p> <p>REMI-AI DDM does not mark REMI EEG records in real time and does not provide any diagnostic conclusion about the patient's condition to the user.</p>

Attribute	Subject Device REMI-AI Rapid Detection Module	Primary Predicate Device Ceribell Pocket EEG Device (K191301)	Secondary Predicate Device REMI-AI Discrete Detection Module (K231779)
	<p>diagnostic conclusion about the subject's condition and is intended as a physiological signal monitor. REMI-AI RDM is indicated for use with adult and pediatric patients (6+ years).</p>	<p>will be shown to a user.</p> <p>The Pocket EEG Device does not provide any diagnostic conclusion about the subject's condition and Seizure Detection notifications cannot be used as a substitute for real time monitoring of the underlying EEG by a trained expert.</p>	
Seizure event detection module	REMI-AI RDM is a seizure detection module that analyzes the last 5 minutes of EEG in a rolling window and identifies seizure events.	The Ceribell Pocket EEG seizure detection module analyzes the last 5 minutes of EEG in a rolling window and identifies seizure events.	REMI-AI DDM detects electrographic events in previously acquired EEG data.
Seizure event notifications	<p>When a seizure event is detected, a notification is generated. These notifications are provided to the REMI System (K230933) for interoperable display on the REMI Mobile software.</p> <p>Notifications include identifying an event that has been detected and provides the prevalence values and algorithm confidence.</p> <p>Event notifications are also annotated in the EEG record.</p>	<p>When a seizure event is detected, a notification is generated. The Seizure Detection module also provides notifications of detected seizure by displaying an on-screen message on the Ceribell EEG Recorder and the optional sending of an email message</p>	No notifications are generated
Seizure prevalence	<p>Seizure prevalence is calculated for the 5-minute rolling window.</p> <p>Notifications and annotations include of:</p> <ul style="list-style-type: none"> Prevalence values presented as a percentage which can range from 10% to 100%. 	<p>Seizure prevalence (defined as seizure burden, or the percentage of time epochs classified as seizure) is calculated for the 5-minute rolling window.</p> <p>Notifications and annotations include of:</p> <ul style="list-style-type: none"> Frequent seizure detected if seizure burden is 10% (30 seconds or more) Abundant seizure if greater than or equal to 50% Continuous if greater than or equal to 90% 	<p>Seizure prevalence is not calculated.</p> <p>No seizure prevalence notifications or annotations</p>
Event confidence	<p>Confidence is calculated for detected events. Confidence is a measure that the event is not a false positive.</p> <p>Notifications and annotations includes of:</p> <ul style="list-style-type: none"> Event confidence presented as Low, Moderate, High, or Very 	<p>Event confidence is not calculated.</p> <p>No event confidence included in notifications or annotations</p>	<p>Confidence is calculated for detected events. Confidence is a measure that the event is not a false positive.</p> <p>No notifications are presented.</p> <p>Annotations consist of:</p> <ul style="list-style-type: none"> Event confidence presented as

Attribute	Subject Device REMI-AI Rapid Detection Module	Primary Predicate Device Ceribell Pocket EEG Device (K191301)	Secondary Predicate Device REMI-AI Discrete Detection Module (K231779)
	High (along with corresponding percentage ranges)		Low, Moderate, High, or Very High (along with corresponding percentage ranges)
Time before notifications may be presented	Several minutes	Several minutes	Not applicable
Seizure event review	<p>REMI-AI RDM will annotate EEG records to identify the detected seizure event to aid in EEG review. These events are provided to the REMI System.</p> <p>The REMI System stores EEG records in a standard EEG format for viewing in a qualified EEG viewing software.</p>	<p>Ceribell EEG Portal includes a seizure detection module that will mark EEG records to identify the detected seizure event to aid in EEG review.</p>	<p>REMI-AI DDM will annotate EEG records to identify the detected seizure event to aid in EEG review. These events are provided to the REMI System.</p> <p>The REMI System stores EEG records in a standard EEG format for viewing in a qualified EEG viewing software.</p>
Use environment	The REMI-AI RDM is indicated for use in non-ICU (Intensive Care Unit) healthcare settings.	Ceribell Pocket EEG is used in a professional healthcare facility environment.	The REMI-AI DDM is indicated for use in healthcare or ambulatory settings.
Software/ system user interface	<p>The REMI-AI RDM produces notifications and annotations that are provided to the REMI System (K230933) in an interoperable way.</p> <p>The REMI System was cleared with the ability to conduct interoperable communications for transfer of EEG data for the purpose of analysis modules and receive the outputs of any such analysis.</p> <p>The REMI System displays this information through the REMI Mobile medical application, and provides the RDM outputs as annotations in the EEG record.</p>	Pocket EEG Device EEG Recording Viewer software	<p>The REMI-AI DDM produces annotations that are provided to the REMI System (K230933) in an interoperable way.</p> <p>The REMI System was cleared with the ability to conduct interoperable communications for transfer of EEG data for the purpose of analysis modules and receive the outputs of any such analysis.</p> <p>The REMI System provides the DDM outputs as annotations in the EEG record.</p>
Algorithm inputs	EEG data acquired from REMI Sensors placed on a patient's scalp. REMI Sensors are a component of the REMI Remote EEG Monitoring System.	EEG acquired from a Ceribell EEG headband placed on a patient's scalp. The sensor band is another component of the Ceribell Pocket EEG system	EEG data acquired from REMI Sensors placed on a patient's scalp. REMI Sensors are a component of the REMI Remote EEG Monitoring System.
Data format (viewer software)	Common EEG data formats(e.g. lay-dat) viewable in qualified EEG viewing software	Format is not publicly available. Data is viewable in the Ceribell EEG Portal viewing software	Common EEG data formats(e.g. lay-dat) viewable in qualified EEG viewing software
Clinical validation	Demonstrated through statistical analysis of clinical data	Demonstrated through statistical analysis of clinical data	Demonstrated through statistical analysis of clinical data

Attribute	Subject Device REMI-AI Rapid Detection Module	Primary Predicate Device Ceribell Pocket EEG Device (K191301)	Secondary Predicate Device REMI-AI Discrete Detection Module (K231779)
Predetermined Change Control Plan (PCCP)	PCCP included in submission	N/A	Authorized PCCP

8. Performance Data

REMI-AI RDM 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
Software Verification	Software verification testing was conducted to ensure software meets specified requirements. Interoperability verification testing was conducted to ensure interoperability of REMI-AI RDM with the REMI Remote EEG Monitoring System and to ensure wireless quality of service.
Clinical Validation	The algorithm was tested against a clinical reference to ensure it meets clinical performance requirements (as outlined in Section 11, Clinical Validation)
Human Factors Validation for REMI-AI RDM outputs	REMI-AI RDM EEG notification outputs were evaluated by representative clinicians reviewers to validate usability REMI-AI RDM EEG annotation outputs were evaluated by representative epileptologist reviewers to validate usability

REMI-AI RDM met all predetermined acceptance criteria derived from the above listed tests and demonstrated substantially equivalent performance as compared with the predicate devices.

9. Clinical Study

EEG data from adult and pediatric patients was used to 1) train the REMI-AI RDM algorithm to identify potential electrographic seizure events in a broad patient population, and 2) validate the REMI-AI RDM algorithm ability to identify potential electrographic seizure events within an indicated patient population.

Patients at these sites wore REMI wireless EEG sensors at bilateral frontal and temporoparietal scalp sites alongside standard-of-care 19-channel, full-montage, video-EEG for up to 7 continuous days in Epilepsy Monitoring Units (EMUs) or for up to 3 continuous days during at-home ambulatory EEG monitoring.

The REMI-AI RDM validation data set consisted of 22 patient records with 54 consensus-determined electrographic seizures lasting at least 30 seconds in duration, and 22 patient records with no consensus-determined electrographic seizures, for a total validation sample size of 44. All attempts were made to ensure diverse patient demographics. The consensus-determined electrographic seizures represented in the validation data set include:

- Focal Seizures
- Focal Evolving To Generalized Seizures
- Generalized Seizures

10. Clinical Reference

EEG data used to generate a reference standard for REMI-AI RDM was collected from standard 19+channel wired 10-20 montage EEG records acquired concurrently with REMI 4-channel EEG. Prior to inclusion in the validation data set, all patients' EEG records underwent panel review by 3 independent expert epileptologists. Experts consisted of a panel of 6 epileptologists, holding certification by the American Board of Psychiatry and Neurology or certification by the American Board of Clinical Neurophysiology with Special Competency in Epilepsy Monitoring. Consensus ground truth electrographic seizures and seizure negative determinations were made using the wired EEG records when at least 2 of 3 members identified the presence or absence of an electrographic seizure event.

Training and Clinical Reference Data Overview

Demographics by age are presented in Table 10.1 below.

Age	Train	Train Sz	Train No-Sz	Test	Test Sz	Test No-Sz
Child (≤ 21)	47 (40%)	32 (39%)	15 (43%)	21 (48%)	11 (50%)	10 (45%)
Adult (22+)	70 (60%)	50 (61%)	20 (57%)	23 (52%)	11 (50%)	12 (55%)
Total	117	82	35	44	22	22

Table 10.1. Demographics By Age. Train is the set of patient records used to train the algorithm and Test is the set of patient records used in this validation analysis. (Sz: Seizure Patients, No-Sz: Non-Seizure Patients)

Demographics by gender are presented in Table 10.2 below.

Gender	Train	Train Sz	Train No-Sz	Test	Test Sz	Test No-Sz
Male	53 (45%)	40 (49%)	13 (37%)	21 (48%)	11 (50%)	10 (45%)
Female	64 (55%)	42 (51%)	22 (63%)	23 (52%)	11 (50%)	12 (55%)
Total	117	82	35	44	22	22

Table 10.2. Demographics by Gender. Train is the set of patient records used to train the algorithm and Test is the set of patient records used in this validation analysis. (Sz: Seizure Patients, No-Sz: Non-Seizure Patients)

A summary of electrographic seizure types included in REMI-AI RDM training and validation is presented in Table 10.3 below.

Seizure Type	Train	Test
Focal	257 (47%)	17 (31%)
Focal Evolving To Generalized	45 (8%)	21 (39%)
Generalized	243 (45%)	16 (30%)
Total	545	54

Table 10.3. Electrographic Seizure Type Count. Train is the set of patient records used to train the algorithm and Test is the set of patient records used in this validation analysis.

A summary of the duration of seizure record data, broken down by electrographic seizure type, is presented in Table 10.4 below.

Duration (s)	Focal		Focal Evolving To Generalized		Generalized	
	Train	Test	Train	Test	Train	Test
<10	8 (3%)	0 (0%)	0 (0%)	0 (0%)	58 (24%)	0 (0%)
10-20	50 (19%)	0 (0%)	0 (0%)	0 (0%)	100 (41%)	0 (0%)
21-40	83 (32%)	0 (0%)	0 (0%)	0 (0%)	31 (13%)	9 (56%)
41-60	47 (18%)	6 (35%)	5 (11%)	0 (0%)	44 (18%)	2 (13%)
61-80	25 (10%)	8 (47%)	6 (13%)	0 (0%)	8 (3%)	1 (6%)
81-100	14 (5%)	2 (12%)	10 (22%)	4 (19%)	1 (0%)	2 (13%)

101-120	11 (4%)	1 (6%)	5 (11%)	10 (48%)	1 (0%)	2 (13%)
121+	19 (7%)	0 (0%)	19 (42%)	7 (33%)	0 (0%)	0 (0%)
Total	257	17	45	21	243	16

Table 10.4. Duration of Seizures by Electrographic Seizure Type. Train is the set of patient records used to train the algorithm and Test is the set of patient records used in this validation analysis.

11. Clinical Validation

REMI-AI RDM validation was evaluated against a combined primary endpoint of Sensitivity > 70% and of a False Alarm Rate (FAR) < 0.446 False Positives (FP)/hr. REMI-AI RDM clinical validation testing demonstrated that REMI-AI RDM achieved Event-Level Sensitivity > 70% (with a calculated 95% CI lower bound of 78.9%) and FAR < 0.35 FP/hr (with a calculated CI upper bound of 0.164 FP/hr).

Across all 22 patients with seizures, patient-level Sensitivity was 92.5%, with a 95% CI Lower Bound of 84.8%. Per-patient Sensitivity was 100% for 23 of the 31 patients. At least one known event was detected for all 22 patients with seizures, and every event was detected for 18 of the 22 patients.

Across all 44 patients, the subject-level FAR was 0.117 FP/hr, with a 95% CI Upper Bound of 0.176, and ranged between 0 to 1.03 FP/hr. There were 22 patients that had no more than one FP (including 6 non-seizure patients), and 13 patients that had no FPs (including 6 non-seizure patients).

Clinical Reference Data Overview

Sensitivity by age group and FAR by age group are presented in Table 11.1 below.

Parameter	Pediatric (6-21 years)	Adult (22+ years)
Sensitivity		
Subjects with Seizures	n = 11	n = 11
Event-level Sensitivity	91.2%	85.0%
95% Confidence Interval	80.0, 100.0	68.0, 100.0
Subject-level Sensitivity	94.1%	90.9%
95% Confidence Interval	85.5, 100.0	78.8, 100.0
False Alarm Rate (FAR)		
Total Subjects	n = 21	n = 23
Event-level FAR	0.162 FP/hr	0.070 FP/hr
95% Confidence Interval	0.070, 0.280	0.040, 0.099
Subject-level FAR	0.174 FP/hr	0.064 FP/hr
95% Confidence Interval	0.083, 0.289	0.037, 0.091

Table 11.1. Sensitivity and False Alarm Rate by Age Group (pediatrics vs. adults)

12. Predetermined Change Control Plan (PCCP)

The REMI-AI RDM has been cleared by the US FDA with an Authorized PCCP. The REMI-AI RDM Authorized PCCP outlines authorized modifications intended to improve algorithm performance through expansion of the training data and/or through optimizations of the algorithm. The Authorized PCCP outlines REMI-AI RDM's data management practices (i.e., how data is collected, annotated, curated, stored, retained, controlled, and used), re-training practices, how and when its performance is evaluated.

The Authorized PCCP also defines validation requirements for all algorithm updates. Prior to release, modifications are validated through testing against a previously established validation data set as well as an updated validation data set. Updates to REMI-AI RDM will be implemented per the Authorized PCCP and through the Software Update process described in the user manual. Epitel will update the user manual following implemented changes and notify customers of software updates and of any changes they may experience, and these changes will be described in release notes viewable on the Epitel website.

13. Substantial Equivalence Conclusion

The REMI-AI Rapid Detection Module (RDM) subject device has the same intended use, similar indications for use and incorporates the same fundamental technology as the legally marketed predicate devices to which it was compared. Based on intended use, technological characteristics, and performance testing, it can be concluded that the subject device, REMI-AI RDM, is substantially equivalent to the identified predicate device.