January 3, 2024

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

Re: K231779
Trade/Device Name: REMI AI Discrete Detection Module
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMB
Dated: December 1, 2023
Received: December 1, 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 (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.

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

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)*
K231779

Device Name
REMI-AI Discrete Detection Module (REMI-AI DDM)

Indications for Use *(Describe)*

The REMI-AI Discrete Detection Module (REMI-AI DDM) is indicated for the analysis of REMI Remote EEG Monitoring System electroencephalogram (EEG) recordings. 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).

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.

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.

REMI-AI Discrete Detection Module (REMI-AI DDM)
510(k) SUMMARY

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

Secondary Contact Information
Christopher M. Phillips
VP, Regulatory Affairs and Quality

Date Prepared
December 27, 2023

2. Subject Device Information

Name of Device: REMI-AI Discrete Detection Module (REMI-AI DDM)
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 Device

Name of Device: Persyst 14 EEG Review and Analysis Software
510(k) Number: K182181
Manufacturer: Persyst Development Corporation

4. Device Description

REMI-AI Discrete Detection Module (REMI-AI DDM) is a software as a medical device (SaMD) that automatically identifies and annotates discrete seizure-like events in previously acquired electroencephalography (EEG) traces to aid a qualified physician in their review of REMI EEG records. REMI-AI DDM analyzes previously acquired EEG data from 4-channel recordings obtained from bilateral, bipolar scalp EEG recordings at both the frontal and temporoparietal regions, collected and stored by the REMI Remote EEG Monitoring System. REMI-AI DDM analyzes EEG recordings and detects regions of the data that may correspond to electrographic seizures lasting at least 10 seconds in duration. These regions are annotated in the REMI EEG file as discrete events and are provided to assist in REMI EEG review.

5. Indications for Use

The REMI-AI Discrete Detection Module (REMI-AI DDM) is indicated for the analysis of REMI Remote EEG Monitoring System electroencephalogram (EEG) recordings. 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).

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.

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*, a predicate device has been selected. Potential predicates were reviewed and the Persyst 14 EEG Review and Analysis Software 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.

7. Substantial Equivalence

REMI-AI DDM 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 DDM to its predicate device, Persyst 14. REMI-AI DDM 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 device.

7.1 Summary of Technological Characteristics and Substantial Equivalence to Predicate Device

Attribute	**Subject Device** REMI Discrete Detection Module (REMI-AI DDM) (K231779)	**Predicate Device** Persyst 14 EEG Review and Analysis Software (K182181)
Classification and Regulation	Class II per 21 CFR 882.1400 Automatic Event Detection Software for Full-Montage Electroencephalograph	Class II per 21 CFR 882.1400 Automatic Event Detection Software for Full-Montage Electroencephalograph
FDA Product Code(s)	OMB	OMB
Intended Use	Automatically identify and annotate events of interest in electroencephalograph traces to aid with EEG review.	Provide a means for review of EEG data, and automatically identify and annotate events of interest in electroencephalograph traces to aid with EEG review.
Indications for Use	The REMI-AI Discrete Detection Module (REMI-AI DDM) is indicated for the analysis of REMI Remote EEG Monitoring System electroencephalogram (EEG) recordings. 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). 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.	1. Persyst 14 EEG Review and Analysis Software is intended for the review, monitoring and analysis of EEG recordings made by electroencephalogram (EEG) devices to aid neurologists in the assessment of EEG. This device is intended to be used by qualified medical practitioners who will exercise professional judgment in using the information. 2. The Seizure Detection and Seizure Probability component of Persyst 14 is intended to mark previously acquired sections of the adult (greater than or equal to 18 years) EEG recordings that may correspond to electrographic seizures, in order to assist qualified clinical practitioners in the assessment of EEG traces. EEG recordings should be obtained with a full scalp montage according to the standard 10/20 system. … 9. This device does not provide any diagnostic conclusion about the patient's condition to the user.
Presentation of Seizure activity	Seizure activity is marked in the EEG trace to be viewed in an EEG viewing software	Seizure activity is marked in the EEG trace to be viewed in an EEG viewing software
Physiological Signal Acquired	Previously collected Electroencephalogram (EEG) data collected from the scalp	Previously collected Electroencephalogram (EEG) data collected from the scalp
Compatible EEG source data	4 channels of EEG data collected from bilateral, bipolar scalp at both the frontal and temporoparietal regions gathered from REMI Sensors	Multiple channels of EEG collected from the scalp at standard locations from a full montage according to the standard 10/20 system

8. Performance Data

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

REMI-AI DDM was tested to verify its design and to validate its safe and effective use for the intended population and use environments. Testing included the following:

Test Type	Summary
Software Verification	Software verification testing conducted to ensure software meets specified requirements
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 DDM outputs	REMI-AI DDM outputs were evaluated by representative epileptologist reviewers to validate the usability of the annotations

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

9. Clinical Study

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

EEG data used to generate a reference standard for REMI-AI DDM 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 subjects' 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.

The REMI-AI DDM validation data set consisted of 31 patient records with 87 consensus-determined electrographic seizures lasting at least 10 seconds in duration, and 19 patient records with no consensus-determined electrographic seizures, for a total validation sample size

of 50. All attempts were made to ensure diverse subject demographics. The consensus-determined electrographic seizures represented in the validation data set include:

- Focal
- Focal Evolving to Generalized
- Generalized

10. Clinical Reference

EEG data used to generate a reference standard for REMI-AI DDM 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)	43 (40%)	31 (42%)	12 (34%)	24 (48%)	13 (42%)	11 (58%)
Adult (22+)	65 (60%)	42 (58%)	23 (66%)	26 (52%)	18 (58%)	8 (42%)
Total	108	73	35	50	31	19

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	46 (43%)	32 (44%)	14 (40%)	26 (52%)	17 (55%)	9 (47%)
Female	62 (57%)	41 (56%)	21 (60%)	24 (48%)	14 (45%)	10 (53%)
Total	108	73	35	50	31	19

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)

Demographics by EEG monitoring environment are presented in Table 10.3 below.

Environment	Train	Train Sz	Train No-Sz	Test	Test Sz	Test No-Sz
EMU	85 (79%)	59 (81%)	26 (74%)	38 (76%)	27 (87%)	11 (58%)
Ambulatory	23 (21%)	14 (19%)	9 (26%)	12 (24%)	4 (13%)	8 (42%)
Total	108	73	35	50	31	19

Table 10.3. Demographics by Monitoring Environment. 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. (EMU: Epilepsy Monitoring Unit, Sz: Seizure Patients, No-Sz: Non-Seizure Patients)

A summary of electrographic seizure types included in REMI-AI DDM training and validation is presented in Table 10.4 below.

Seizure Type	Train	Test
Focal	254 (45%)	22 (25%)
Focal Evolving to Generalized	39 (7%)	35 (40%)
Generalized	269 (48%)	30 (34%)
Total	562	87

Table 10.4. 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 10.5 below.

	Focal		Focal Evolving To Generalized		Generalized	
Duration (s)	Train	Test	Train	Test	Train	Test
<10	9 (4%)	0 (0%)	0 (0%)	0 (0%)	76 (28%)	0 (0%)
10-20	51 (20%)	4 (18%)	0 (0%)	0 (0%)	100 (37%)	14 (47%)
21-40	80 (31%)	1 (5%)	0 (0%)	0 (0%)	40 (15%)	7 (23%)
41-60	45 (18%)	7 (32%)	5 (13%)	2 (6%)	43 (16%)	2 (7%)
61-80	25 (10%)	7 (32%)	6 (15%)	6 (17%)	6 (2%)	3 (10%)
81-100	15 (6%)	1 (5%)	10 (26%)	5 (14%)	3 (1%)	2 (7%)
101-120	9 (4%)	1 (5%)	3 (8%)	10 (29%)	1 (0%)	1 (3%)
121+	20 (8%)	1 (5%)	15 (38%)	12 (34%)	0 (0%)	1 (3%)
Total	254	22	39	35	269	30

Table 10.5. 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 DDM validation was evaluated against a combined primary endpoint of Sensitivity > 70% and of a False Alarm Rate (FAR) < 0.35 FP/hr. REMI-AI DDM clinical validation testing demonstrated that REMI-AI DDM achieved Event-Level Sensitivity > 70% (with a calculated 95% CI lower bound of 79.5%) and FAR < 0.35 False Positives (FP)/hr (with a calculated CI upper bound of 0.221 FP/hr).

Across all 31 patients with seizures, the event-level Sensitivity was 86.2%. The Mean Per-Patient Sensitivity was determined to be 92.2%, with a 95% CI Lower Bound of 86.5%, and ranged between 50% to 100%. Per-Patient Sensitivity was 100% for 23 of the 31 patients. At least one known event was detected for all 31 patients with seizures.

Across all 50 patients, the event-level FAR was 0.162 FP/hr (with 415 FP for 2,562.5 hours of data). The Mean Per-Patient FAR was determined to be 0.176 FP/hr, with a 95% CI Upper Bound of 0.230, and ranged between 0 to 0.929 FP/hr. There were 17 patients with FARs ≤ 0.08 FP/hr, 8 patients with no more than one FP (including 4 non-seizure patients), and 4 patients with no FP, including 2 non-seizure patients.

Clinical Reference Data Overview

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

Parameter	Pediatric (6-21 years)	Adult (22+ years)
Sensitivity		
Subjects with Seizures	n = 13	n = 18
Event-level Sensitivity	83.0%	90.0%
95% Confidence Interval	73.1, 93.3	81.5, 100.0
Subject-level Sensitivity	87.8%	95.5%
95% Confidence Interval	77.0, 97.0	90.0, 100.0
False Alarm Rate (FAR)		
Total Subjects	n = 24	n = 26
Event-level FAR	0.227 FP/hr	0.131 FP/hr
95% Confidence Interval	0.131, 0.335	0.085, 0.197
Subject-level FAR	0.223 FP/hr	0.132 FP/hr
95% Confidence Interval	0.146, 0.316	0.088, 0.190

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

Sensitivity and FAR by monitoring environment is presented in Table 11.2 below.

Parameter	EMU	Ambulatory
Sensitivity		
Subjects with Seizures	n = 27	n = 4
Event-level Sensitivity	87.5%	80.0%
95% Confidence Interval	80.0, 94.4	71.0, 100.0
Subject-level Sensitivity	92.2%	92.5%
95% Confidence Interval	85.9, 97.3	77.5, 100.0
False Alarm Rate (FAR)		
Total Subjects	n = 38	n = 12
Event-level FAR	0.136 FP/hr	0.290 FP/hr
95% Confidence Interval	0.089, 0.194	0.170, 0.434
Subject-level FAR	0.138 FP/hr	0.294 FP/hr
95% Confidence Interval	0.096, 0.187	0.184, 0.440

Table 11.2. Sensitivity and False Alarm Rate by Monitoring Environment (EMU vs. Ambulatory environment).

12. Predetermined Change Control Plan (PCCP)

The REMI-AI DDM has been cleared by the US FDA with an Authorized PCCP. The REMI-AI DDM 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 DDM'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 DDM 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 Discrete Detection Module (DDM) 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, Persyst 14 EEG Review and Analysis Software. Based on intended use, technological characteristics, and performance testing, it can be concluded that the subject device, REMI-AI DDM, is substantially equivalent to the identified predicate device.