



Food and Drug Administration
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May 15, 2015

Picofemto LLC
Srikant Krishna
Founder and CEO
228 East 45th St., 2nd Floor
New York, NY 10001

Re: K141883

Trade/Device Name: CliniScanSM EEG
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMB, OLT
Dated: April 13, 2015
Received: April 14, 2015

Dear Mr. Krishna:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K141883

Device Name

CliniScanSM EEG

Indications for Use (Describe)

1. CliniscanSM EEG is a clinical decision support system for medical data, to assist healthcare professionals in the visualization and analysis of EEG data.
2. The Seizure Detection component of CliniscanSM EEG is intended to mark previously acquired sections of 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.
3. CliniscanSM EEG is intended for use on EEG recordings acquired using full scalp montage according to the standard 10/20 system.
4. The user may annotate the data, and the annotations are stored with the EEG recording in the cloud.
5. CliniscanSM EEG displays standard qEEG features to the user including FFT Power Spectrum, Coherence Mapping (EEG Activity Mapping), Density Spectral Array, EEG Localization Maps, and Wavelet Subband Decomposition (Delta, Theta, Alpha, Beta, and Gamma).
6. CliniscanSM EEG detects seizure events for review by qualified medical professionals.
7. CliniscanSM EEG is designed to provide analytics data derived from a patient's input EEG data. It is NOT designed to provide definitive diagnoses of diseases or treatments of ailments.

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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510(k) Summary

A summary of safety and effectiveness information in accordance with 21 CFR 807.92

Submitter: Picofemto LLC

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Contact Person: Srikant Krishna

Phone Number: (212) 502-3770

Fax Number: (212) 502-0818

Date Prepared: 04/13/2015

Trade Name: CliniscanSM EEG

Common Name: Electroencephalogram (EEG) signal spectrum and source analyzer

Classification Name: (OMB) Automatic event detection software for full-montage electroencephalograph and (OLT) qEEG

Regulation Number: 21 CFR 882.1400

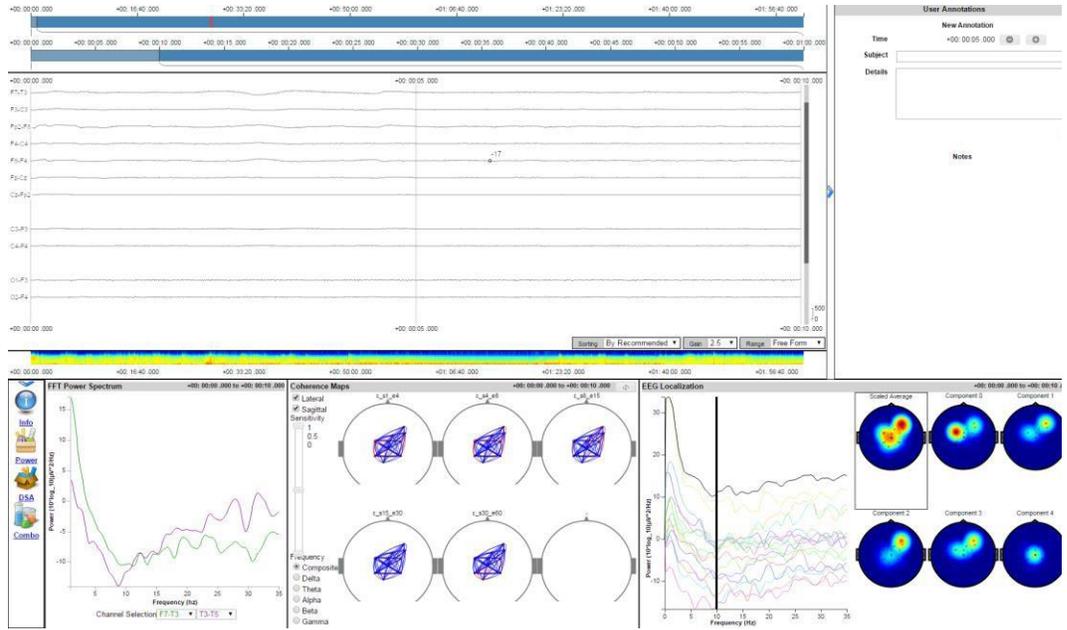
Predicate Devices: The CliniscanSM EEG is substantially equivalent to the Persyst[®] Reveal [FDA 510(k) number K011397] and Neurosoft Curry 7 [FDA 510(k) number K001781].



Device Description

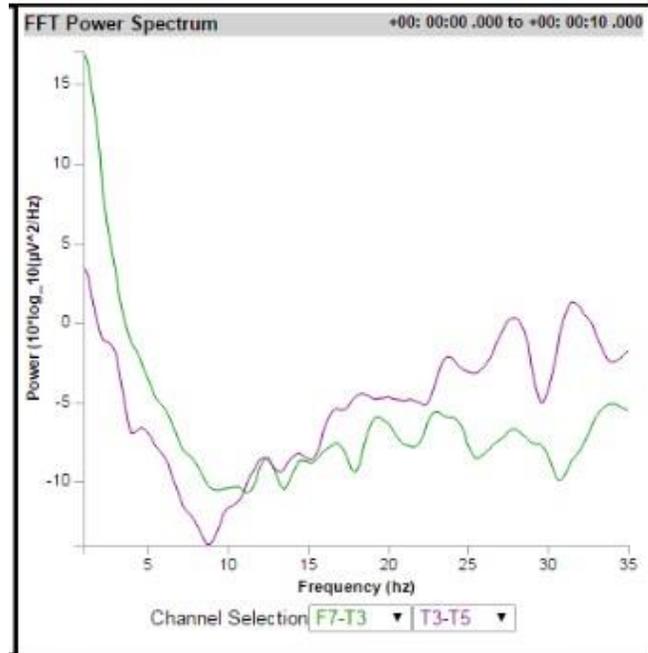
CliniscanSM EEG, a PicoFemto product, is a clinical decision support system for medical data, designed to assist healthcare professionals in the visualization and analysis of EEG data. The device provides seizure event detection and calculates many qEEG (quantitative EEG) parameters for display to the user. All analysis (seizure detection and qEEG) are displayed in conjunction with the original EEG recording for review by experts and are designed to be reviewed in the context of the original data.

The CliniscanSM EEG visualizer provides a user-friendly environment for displaying the available qEEG parameters along with the original EEG recording (see below). The EEG recording display window, time bar, and User Annotations frames remained fixed within the visualizer; however, the bottom portion of the screen contains tabs for the user to navigate the qEEG features. The user may access the FFT Power Spectrum, Coherence Maps, and EEG Topography Maps under the “Combo” tab; Wavelet Subband Decomposition and the FFT Power Spectrum (again) are located under the “Power” tab; the “DSA” tab contains only the Density Spectral Array display.

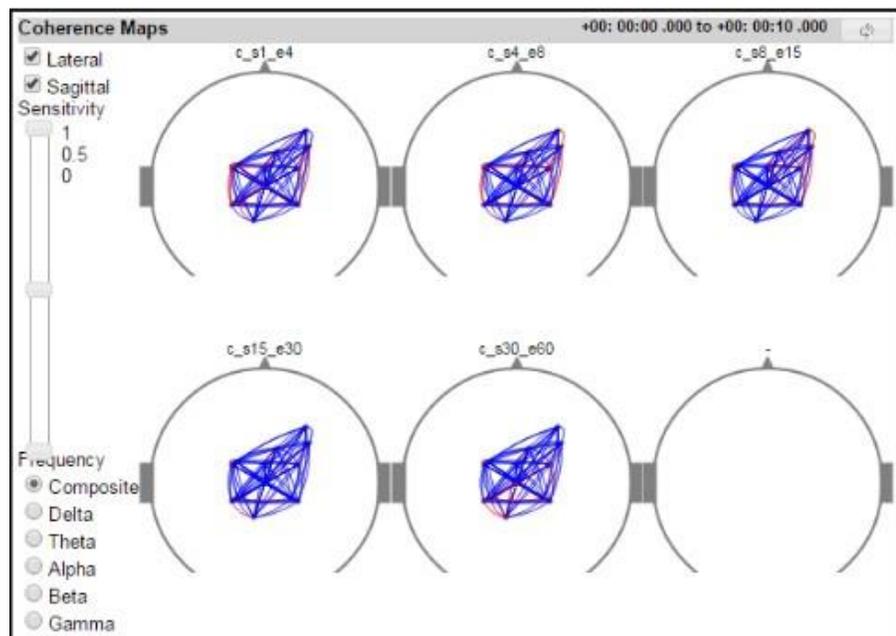


After uploaded an EEG in EDF format, the user may view the following qEEG Parameters:

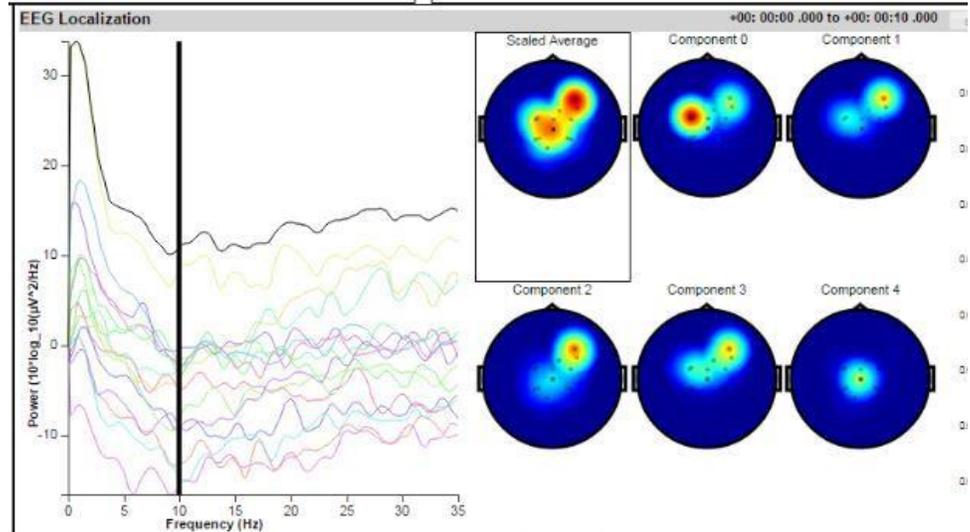
- 1) FFT Power Spectrum – The user can select any two channels to view an FFT Power Spectrum of Power vs. Frequency between the two channels.



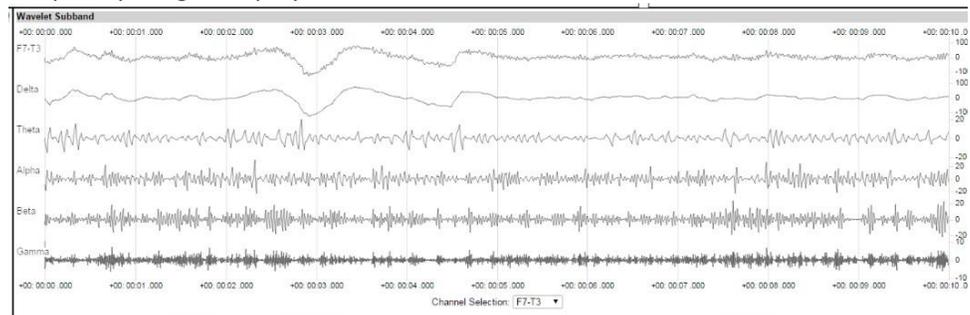
- 2) Coherence Maps – Coherence maps are displayed to the user, allowing the user to define cut-off values ranging from 0-1 and the frequency of interest (composite, delta, theta, alpha, beta, or gamma). As the user-defined parameters are adjusted, the six maps display the corresponding coherence. The user may also select to view Lateral, Sagittal, or both types of coherence.



- 3) EEG Topographical Maps – EEG Topographical Maps maps and a corresponding Power vs. Frequency graph are displayed to the user. The maps are calculated using independent component analysis, and the top four components along with the scaled average are displayed to the user. The relative powers of the independent components are displayed in which the higher power corresponds to the top (red) part of the spectrum. The absolute power of these components is not necessary, and, therefore, is not displayed to the user.

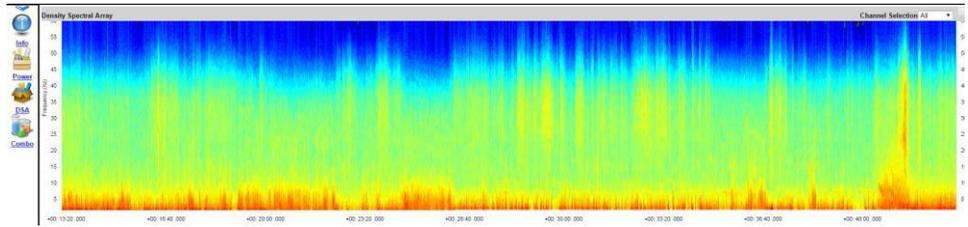


- 4) Wavelet Subband Decomposition –The user may select a channel of interest to view the different frequencies of said channel broken down into the five main frequency bands of interest: Delta, Theta, Alpha, Beta, and Gamma. The original channel is displayed at the top of the graph, with the corresponding frequency ranges displayed in the same time frame beneath the channel.



- 5) Density Spectral Array (DSA) – The DSA display updates for each user-selected time-window. Additionally, the user may select which channels to include in

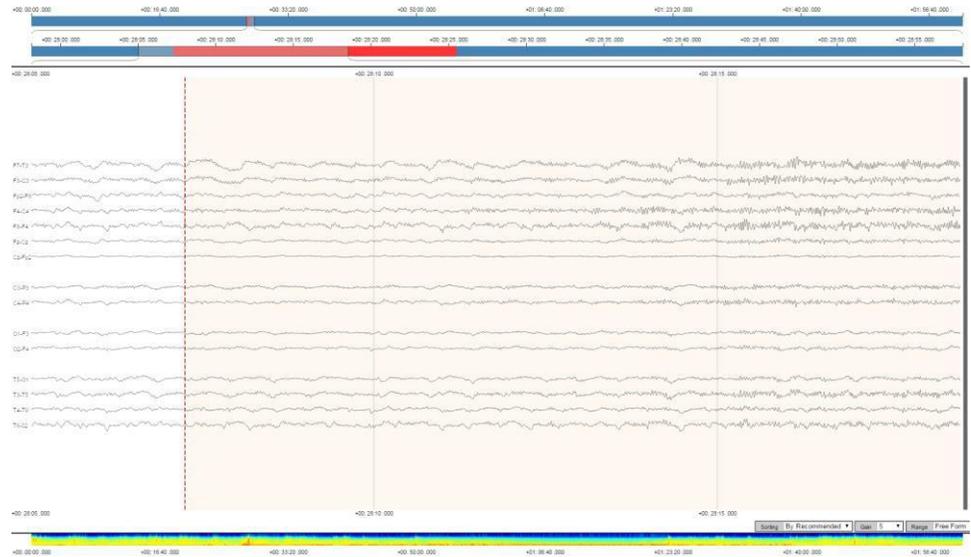
the DSA calculation.



- 6) User Annotations – The user may add annotations including the time of the event, the subject name, and any important details. These annotations are saved with the recording in the cloud.

A screenshot of a 'User Annotations' form. The form has a title bar 'User Annotations' with a refresh icon. Below the title bar is a section 'New Annotation'. It contains three fields: 'Time' with a value of '+00: 00.05 .000' and two arrow buttons; 'Subject' with a text input field; and 'Details' with a larger text area. At the bottom right is a 'Create' button. Below the form is a 'Notes' section with a scroll bar.

- 7) Seizure Event Detection – The visualizer automatically displays the results of the seizure event detection algorithm for the user to review. The event is indicated by a small red block marked on the overall time bar, followed by a larger red block marked on the user-selected time-bar. Within the channel display, the onset and offset of the detected seizure are indicated using red dashed lines, and the inclusive time window is highlighted a tan color to differentiate from the non-seizure windows.



- 8) Info – Under the “Info” tab, additional details are available to the user as selectable text (may be copied and pasted). This information includes Analysis Details, Incidents (seizure events with onset and offset time), and Channels.

CliniscanSM EEG is designed to provide industry standard analytics data derived from a patient’s input EEG data. It is **NOT** designed to provide definitive diagnoses of diseases or treatments of ailments.

Technology Description

CliniscanSM EEG detects and marks possible seizure events on previously acquired EEG recordings for review by qualified medical professionals.



**Intended
Use/Indications
for Use:**

1. CliniscanSM EEG is a clinical decision support system for medical data, to assist healthcare professionals in the visualization and analysis of EEG data.
2. The Seizure Detection component of CliniscanSM EEG is intended to mark previously acquired sections of 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.
3. CliniscanSM EEG is intended for use on EEG recordings acquired using full scalp montage according to the standard 10/20 system.
4. The user may annotate the data, and the annotations are stored with the EEG recording in the cloud.
5. CliniscanSM EEG displays standard qEEG features to the user including FFT Power Spectrum, Coherence Mapping (EEG Activity Mapping), Density Spectral Array, EEG Topography Maps, and Wavelet Subband Decomposition (Delta, Theta, Alpha, Beta, and Gamma).
6. CliniscanSM EEG detects seizure events for review by qualified medical professionals.
7. **CliniscanSM EEG is designed to provide analytics data derived from a patient's input EEG data. It is NOT designed to provide definitive diagnoses of diseases or treatments of ailments.**

Device Comparison to Predicate Device:

Features	Persyst Reveal EEG Review and Analysis Software K011397	Curry 7 Multimodal NeuroImaging Software K001781	CliniscanSM EEG Electroencephalogram (EEG) signal spectrum and source analyzer K141883
1. Product Code	OMB/OLT	OLX	OMB/OLT
2. Product Class	II	II	II
3. EEG Modality Compatible	Yes	Yes	Yes
4. Identifies seizures	Yes	No	Yes
5. Intended Use Age Range	Pediatric and Adult	Pediatric and Adult	Adult (18+)
6. Montage/Channel Array	Scalp 10/20 Array	Custom and Scalp 10/20 Array	Scalp 10/20 Array
7. Type of EEG analysis	Post-hoc	Real-time and post hoc	Post-hoc
8. Data storage	Yes	Yes	Yes
9. Artifact Reduction	Yes	Yes	Yes
10. Wavelet sub band decomposition	Yes	Yes	Yes
11. Density spectral maps	Yes	No	Yes
12. FFT Power Spectrum	Yes	Yes	Yes
13. EEG Topographical Maps	Yes	Yes	Yes
14. Coherence Maps (EEG Brain Mapping)	No	Yes	Yes
15. User-defined parameters for display purposes	Yes	Yes	Yes
16. Cloud based	No	No, but includes an online signal processing package	Yes
17. Operating Systems	Unknown	Unknown	Windows and MacOS
18. Applicable Web Browsers	N/A	Unknown	Firefox ESR Version 24 Chrome Version 35
19. Computer hardware needed but not provided.	unknown	Unknown	Yes

We have found that CliniscanSM EEG is substantially equivalent to Persyst Reveal for all of the features (1-19) with the exception of Coherence Mapping; however, CliniscanSM EEG is substantially equivalent to Curry 7 regarding the Coherence Mapping feature (See Explanation 14. *Coherence Mapping* below).

1. **Product Code:** Persyst Reveal and PicoFemto's CliniscanSM EEG both fall under product code OMB with a secondary product code OLT. Both devices mark events in previously acquired EEG recordings with supplemental quantitative EEG analysis.
2. **Product Class:** Both devices are a product class II due to the possibility of a medical professional relying on device output to determine patient diagnosis. Neither device attempts to diagnose a disease or ailment of any kind, and results must always be reviewed by qualified medical professionals.
3. **EEG Modality Compatible:** Both devices are intended to take previously acquired EEG recordings and analytically process the data.
4. **Identifies Seizures:** Both devices detect seizure activity. CliniscanSM EEG detects seizures by highlighting the window of the suggested event location. Persyst Reveal provides an equivalent single bar with the seizure event indicated.
5. **Intended Use Age Range:** Both devices are intended for use in adults; however, Persyst Reveal includes pediatric use for seizure detection.
6. **Montage/Channel Array:** Both devices are compatible with a standard 21-channel 10/20 monopolar montage using scalp electrodes.
7. **Type of EEG Analysis:** Both devices are intended for use in post-hoc analysis of EEG recordings. Neither device is meant to detect events in real-time analysis or to administer any medication based on detected events.
8. **Data Storage:** Both devices offer data storage so the user only needs to upload the EEG recording one-time. In CliniscanSM EEG, data is stored safely on the cloud for the user to access from any compatible device.
9. **Artifact Reduction:** Both products offer artifact reduction using overlapping epochs to remove artifacts resulting from muscle twitches, eye movement, electrical, heartbeat, tongue and chewing. Persyst Reveal offers artifact reduction based on a user selection using blind source separation algorithms. CliniscanSM uses measures of Kurtosis in back-end processing to automatically remove artifacts.
10. **Wavelet Sub-band Decomposition:** Both devices decompose brain waves into alpha (8-12 Hz), beta (13-30 Hz), delta (<3 Hz), theta (4-7 Hz), and gamma (30-100 Hz) waves.
11. **Density Spectral Maps:** Persyst Reveal and CliniscanSM EEG both derive a color density spectral array map using the results from the Fast Fourier Transform to calculate and display the power spectrum.
12. **FFT Power Spectrum:** Both devices use FFT to produce a graphical output of amplitude verses frequency (Power Spectrum) for a reader to view the overview of a long period EEG in the frequency range.
13. **EEG Topographical Maps:** Persyst Reveal and CliniscanSM EEG both display EEG topographical maps available to the user. CliniscanSM EEG uses independent component analysis to generate a heat map indicating the relative power of independent component activity at each electrode. Persyst Reveal uses a similar approach by displaying a topographic map of the voltage and frequency concentrated at each electrode. There is no substantial technological difference between how each device chooses to calculate and display EEG Topographical Maps.
14. **Coherence Mapping:** All three devices calculate coherence using the same methodology; however, CliniscanSM EEG and Curry 7 provide a simple coherence visualization for the user to view. They both display coherence values on a generic image merely to aid the user in identifying electrode locations, as opposed to placing them in a table. Although Curry 7 is a

multimodal device, the Signal Processing Module available with Curry 7 only uses the EEG data acquired for qEEG calculations (including coherence), which is equivalent to the coherence calculated and displayed by CliniscanSM EEG.

Coherence Mapping does not change the intended use or safety and effectiveness of the device when compared to Curry 7 because both devices still intend to aid a qualified EEG expert in the visualization and analysis of the electrical activity of the brain found in EEG recordings. Curry 7 provides an almost identical and functionally equivalent Coherence Map for the user to view coherence between electrodes, including 2D maps and user-defined threshold values.

Therefore, there is no substantial difference in safety or effectiveness of CliniscanSM EEG's Coherence Mapping versus predicate Curry 7.

15. **User-defined parameters for display purposes:** Both devices offer user-defined parameters for display purposes. Persyst Reveal offers a user-defined threshold to detect seizure events with an increased sensitivity at a cost of increased false detections per hour. CliniscanSM offers user-defined parameters for determining coherence between different parts of the brain. There is no suggested initial parameter threshold, and the results are displayed based on the user-defined threshold (0-1).
16. **Cloud Based:** Persyst Reveal requires locally downloaded software; CliniscanSM EEG is built in the cloud with cloud storage, making it much more easily accessible.
17. **Operating Systems:** CliniscanSM EEG is compatible with both Windows and Macintosh operating systems. The compatible operating systems for Persyst Reveal is unknown; however, this feature does not introduce any questions of safety or effectiveness.
18. **Web Browsers:** CliniscanSM EEG works on both FireFox ESR 24 and Google Chrome 35. This feature is not applicable to Persyst Reveal since no web browser is necessary; however, this feature does not introduce any questions of safety and effectiveness.
19. **Computer hardware needed but not provided:** Persyst Reveal: Unknown. CliniscanSM EEG: Minimum Screen size: 13", Recommended screen size: 20", Minimum amount of RAM: 4Gb, Recommended: 8Gb, Minimum Processor Speed: 1Ghz, Minimum display width of 1366 pixels and minimum display height of 768 pixels, Recommended display width is 1920 pixels and recommended display height is 1200 pixels. This feature does not introduce any questions of safety and effectiveness.

Predicate Device Comparison Conclusion: CliniscanSM EEG has the same intended use/indications for use and technological features as the predicate Persyst Reveal with no new questions of safety and effectiveness. Persyst Reveal and CliniscanSM EEG differ in that CliniscanSM EEG additionally provides Coherence Mapping equivalent to Curry 7; however, this feature does not introduce any additional questions of safety and effectiveness. Persyst Reveal and CliniscanSM EEG are both designed to assist qualified medical professionals through the use of qEEG tools and automatic seizure event detection for post-hoc analysis of EEG recordings.

Non-Clinical Performance Data:

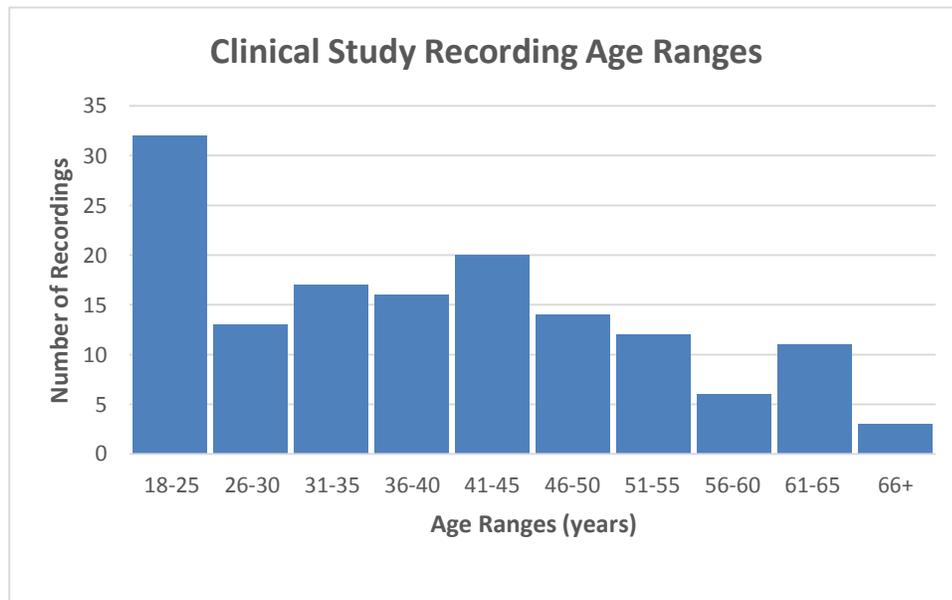
Testing was performed at the unit, integration, and functional/system levels and included verification testing of algorithms and risk control measures. Synthetic data was used to test ICA, Coherence, FFT, and Seizure Detection. Furthermore, archived clinical data from multiple sites was used to train and validate the internal parameters involved in seizure detection.

Clinical Study Data:

A clinical study was conducted to demonstrate substantial safety and effectiveness when CliniscanSM EEG’s event detection algorithm is compared to ground truth (two-thirds majority rule of manual markings by EEG experts). These claims are supported by evaluating the Positive Percent Agreement (PPA) and False Positives per hour (Fp/H) of CliniscanSM EEG verses ground truth, each EEG expert verses the compiled ground truth, and comparison to previous results from predicate Persyst Reveal.

Subject Population and Test Data Set

CliniscanSM EEG was evaluated using 144 subjects for seizure determination acquired from the Epilepsy Monitoring Unit (EMU). Recordings are attained as archived clinical data from subjects 18 years of age and greater. Each recording lasts approximately 2 hours for a total of about 293 hours of EEG recordings. Roughly 20% of the recordings are “normal”, coming from subjects with no history of seizures; each recording contains no more than 4 seizures to reduce bias and heavily weighted results. After ground truth determination, 134 seizures were identified in the clinical study collection. All recordings were previously acquired using a standard 10-20 montage scalp EEG and saved down in .edf format.



Reference Standard (Ground Truth)

Each of the 144 recordings were manually marked for seizure onset and offset by three independent and blinded EEG experts. Each expert was provided with a basic EEG visualizer loaded onto a remote machine along with the previously acquired EEG recordings. The end point for the clinical study was for each EEG expert to manually mark any seizure events located in the collection of EEG recordings. Due to the expected inter-rater variability, a two-thirds majority rule was used to determine the ground truth for seizure presence.

Statistical Analysis

1) Inter-rater Performance for Seizure Detection

Each rater is compared to every other rater to find their relative PPA and Fp/H. The PPAs ranged from 0.77-0.90 and the Fp/H ranged from 0.13-0.20. These ranges are typical for acceptable predicate devices; therefore, the inter-rater agreement is sufficient for compiling a 2/3 majority ground truth.

	Rater 1		Rater 2		Rater 3	
	PPA	Fp/H	PPA	Fp/H	PPA	Fp/H
Rater 1	-	-	0.90	0.14	0.84	0.13
Rater 2	0.90	0.14	-	-	0.77	0.16
Rater 3	0.84	0.16	0.77	0.20	-	-

2) Algorithm Seizure Detection Analysis

The same recordings marked by all three EEG experts were ran through the CliniscanSM EEG event detection algorithm. The algorithm results are compared to the compiled ground truth using PPA and Fp/H (See eq.1 and eq.2). A bootstrap method is compiled to create a 95% confidence interval to compare the algorithm to ground truth.

$$PPA = \frac{\# \text{ of True Positives}}{\# \text{ of True Positives} + \text{False Negatives}} \text{ (Eq. 1)}$$

$$Fp/H = \frac{\# \text{ of False Detections}}{\text{hour of EEG Recording}} \text{ (Eq. 2)}$$

Results

CliniscanSM results are obtained from the clinical study designed specifically for testing CliniscanSM. The CliniscanSM EEG's seizure detection algorithm was compared to the ground truth to determine PPA and Fp/H.

	[Lower Limit, Upper Limit]	Original Mean	Bias	Bias-corrected Mean	Standard Error
PPA (95% C.I.)	[0.687,0.857]	0.7835	0.0011	0.7846	0.042
Fp/H (95% C.I.)	[0.325,0.540]	0.4164	-0.0002	0.4162	0.054

Conclusion

Based on the non-clinical and clinical testing, we believe CliniscanSM EEG provides automatic EEG seizure event detection which introduces no new questions of safety and effectiveness. Furthermore, CliniscanSM EEG's features are substantially equivalent to predicate Persyst Reveal, presenting no new questions of safety or effectiveness.