



December 17, 2019

Moberg Research, Inc.
Anna Rodriguez, Ph.D.
Director of Research
224 S. Maple Street
Ambler, Pennsylvania 19002

Re: K192572

Trade/Device Name: CNS Envision
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMA, OLT, ORT
Dated: September 17, 2019
Received: September 18, 2019

Dear Dr. Anna Rodriguez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

510(k) Number (if known)

K192572

Device Name

CNS Envision

Indications for Use (Describe)

CNS Envision is intended for use by qualified personnel in the review, annotation, and analysis of patient data collected using external physiological monitors. These data are: raw and quantitative EEG, recorded video data, generic vital signs, electrocardiography, electromyography, intracranial pressures, transcranial Doppler measurements, and Glasgow Coma Score.

CNS Envision includes the calculation and display of a set of quantitative measures intended to monitor and analyze the EEG waveforms. These include, for example, frequency bands, asymmetry, and burst suppression. These quantitative EEG measures should always be interpreted in conjunction with review of the original EEG waveforms.

The aEEG functionality included in CNS Envision is intended to monitor the state of the brain.

CNS Envision is intended for use by a physician or other qualified medical personnel who will exercise professional judgement in using the information. It is intended for use on patients of all ages.

This device 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.

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K192572

Traditional 510(k) Summary

This 510(k) summary was prepared to provide an understanding of the basis for the determination of substantial equivalence in accordance with the requirements 21 CFR 807.92.

Submitter:	Moberg Research, Inc. 224 S. Maple Street Ambler, PA 19002 (215)283-0860
Contact Person:	Anna Rodriguez, Product Manager anna@moberg.com
Date Prepared:	December 17, 2019
Trade Name:	CNS Envision
Regulation Name:	Electroencephalograph
Regulation Number:	21 CFR 882.1400
Regulatory Classification:	Class II
Product Codes:	OMA amplitude-integrated electroencephalograph (aEEG) (Primary Procode) OLT non-normalizing quantitative electroencephalograph (EEG) software ORT burst suppression detection software for electroencephalograph
Review Panel:	Neurological and Physical Medicine Devices (OHT5)

Neurosurgical, Neurointerventional and Neurodiagnostic Devices (DHT5A)

Predicate Device: **K080217** Component Neuromonitoring System (Primary Predicate)
K182181 Persyst 14 EEG Review and Analysis Software

Device Description: CNS Envision is a Microsoft Windows-based software application that facilitates the review, annotation, and analysis of patient data and physiological measurements. Some of these data, such as ECG, are displayed in raw format whereas other types, such as EEG, are analyzed and quantified by the software.

The specific type of input data that are reviewable by CNS Envision software are:

- Raw electroencephalography (EEG)
- Quantitative EEG trends; density spectral arrays (DSA) spectral edge frequency (SEF), alpha-delta ratio (ADR), and amplitude EEG (aEEG)
- Video
- Generic vital signs which are heart rate (HR), respiration rate (RR), pulse oximetry (SpO2), blood pressure, arterial blood pressure (ABP), mean arterial pressure (MAP), and body temperature
- Electrocardiography (ECG)
- Electromyography (EMG)
- Intracranial pressure (ICP)
- Transcranial Doppler (TCD) measurements (e.g. spectral envelope, peak velocity, and pulsatility index; TCD measurement is collected by the predicate K080217 device's interface module which interfaces with the Spencer TCD device cleared in K002533, which was a predicate to the predicate K080217
- Glasgow Coma Score (GCS); this parameter is manually entered on the CNS Monitor (K080217) with 3 total GCS scores by the user; the CNS software automatically sums the 3 scores and stores the data to provide a trend graph

CNS Envision also has several features to enable ease-of-use. For example, users may select customized layouts that provide data displays that can be tailored to their monitoring needs according to data sources. The subject device also offers customizable EEG montages that present raw EEG data to medical personnel for interpretation.

Unlike the predicate device, Component Neuromonitoring System™, the subject device does not perform direct data acquisition. Instead, it offers the ability to review data remotely or adjust the review speed.

Intended Use: The CNS Envision software is intended to be used for post-hoc analysis of electroencephalograph (EEG) data using conventional methodology to output and display standard EEG parameters for interpretation by a qualified user.

The device uses software algorithms as a tool to analyze EEG and other physiological recordings, and to calculate conventional EEG parameters. (e.g. spectral edge frequency, percent alpha, asymmetry).

This device does not provide any diagnostic conclusion about the patient's condition to the user as part of its output. The software does not contain automated detection algorithms.

Table 1: Comparison of Indications for Use to Primary Predicate

Primary Predicate K080217 <i>Component Neuromonitoring System</i>	Subject Device K192572 <i>CNS Envision</i>	<i>Comments regarding comparison and differences</i>
The Component Neuromonitoring System™ is intended to monitor the state of the brain by recording and displaying EEG signals, and can also receive and display a variety of vital signs and other measurements from third-party	CNS Envision is intended for use by qualified personnel in the review, annotation, and analysis of patient data collected using external physiological monitors. These data are: raw and quantitative EEG, recorded video data, generic vital	<i>“CNS Envision is intended for use by qualified personnel in the review, annotation, and analysis of patient data collected using external physiological monitors. These data are: raw and quantitative EEG, recorded video data, generic vital signs, electrocardiography,</i>

Primary Predicate K080217 <i>Component Neuromonitoring System</i>	Subject Device K192572 <i>CNS Envision</i>	<i>Comments regarding comparison and differences</i>
monitoring devices (such as ICP, ECG, SpO2, and others). It also has the optional capability to record and display patient video. The Component Neuromonitoring System is intended for use by a physician or other qualified medical personnel. It is intended for use on patients of all ages within a hospital or medical environment, including the operating room, intensive care unit, emergency room, and clinical research settings.	signs, electrocardiography, electromyography, intracranial pressures, transcranial Doppler measurements, Glasgow Coma Score, and cardiac output. CNS Envision includes the calculation and display of a set of quantitative measures intended to monitor and analyze the EEG waveforms. These include, for example, frequency bands, asymmetry, and burst suppression. These quantitative EEG measures should always be interpreted in conjunction with review of the original EEG waveforms. The aEEG functionality included in CNS Envision is intended to monitor the state of the brain. CNS Envision is intended for use by a physician or other qualified medical personnel who will exercise professional judgement in using the information. It is intended for use on patients of all ages.	<i>electromyography, intracranial pressures, transcranial Doppler measurements, Glasgow Coma Score, and cardiac output”</i> CNS Envision supports medical personnel in the review and analysis of patient data collected during neurological monitoring, with particular focus on EEG. The statement describing this capability is consistent with the compared predicate device’s Indications for Use which states: “<u>displaying EEG signals</u>, and can also receive and <u>display a variety of vital signs and other measurements from third-party monitoring devices</u> (such as ICP, ECG, SpO2, and others). It also has the optional capability to record and <u>display patient video.</u>” <i>“CNS Envision includes the calculation and display of a set of quantitative measures intended to monitor and analyze the EEG waveform. These include frequency bands, rhythmic patterns, and burst suppression. These quantitative EEG measures should always be</i>

Primary Predicate K080217 <i>Component Neuromonitoring System</i>	Subject Device K192572 <i>CNS Envision</i>	<i>Comments regarding comparison and differences</i>
	This device does not provide any diagnostic conclusion about the patient's condition to the user.	<i>interpreted in conjunction with review of the original EEG waveforms.”</i> In CNS Envision, the review, monitoring, and analysis of EEG recordings is facilitated by the display of conventional quantitative measures that describe frequency bands, rhythmic patterns, and burst suppression. Such measures are commonly calculated and displayed in other electroencephalographs that belong to the OLT product code, such as the Component Neuromonitoring System™. <i>“The aEEG functionality included in CNS Envision is intended to monitor the state of the brain.”</i> The predicate device is classified under product code OMA, Amplitude-Integrated Electroencephalograph. The statement describing this capability is consistent with that of the compared predicate device: “The Component Neuromonitoring System™ is intended to <u>monitor the state of the brain</u>”.

Primary Predicate K080217 <i>Component Neuromonitoring System</i>	Subject Device K192572 <i>CNS Envision</i>	<i>Comments regarding comparison and differences</i>
		<i>“CNS Envision is intended for use by a physician or other qualified medical personnel who will exercise professional judgement in using the information.”</i> The predicate device makes a statement regarding the required qualifications of the end user(s). Therefore, CNS Envision makes a similar and consistent statement within its Intended Use/Indications for Use. <i>“It is intended for use on patients of all ages.”</i> This is consistent between CNS Envision and the predicate device about the intended age population. <i>“This device does not provide any diagnostic conclusion about the patient’s condition to the user.”</i> Many OLT devices (such as Persyst 14) include a statement about the device not providing diagnostic conclusions. Therefore, we believe it is appropriate to include the above similar and consistent statement for CNS Envision.

Table 2: Comparison of Subject Device's Technological Characteristics to Predicates

	Component Monitoring System Primary Predicate K080217	Persyst 14 EEG Review and Analysis Software K182181	CNS Envision Subject Device K192572	Comments
Physical State	Software-only	Software-only	Software-only	
Device Class	Class II	Class II	Class II	
Class Name	EEG	EEG	EEG	
Classifying Regulation	882.1400	882.1400	882.1400	
Intended User	Medical Professionals	Medical Professionals	Medical Professionals	
User Input	Mouse/Keyboard	Mouse/Keyboard	Mouse/Keyboard	
EEG Parameter Analysis Available	Yes	Yes	Yes	
Notification Available	No	Yes	No	
Data Input	Optional EEG amplifier	EEG data only; user-selected channels	EEG data only; user-selected channels	
Data & Analysis Output	Graph	Graph; Over-threshold notification	Graph	
X-Axis	Linear scale; units of time; user-adjustable	Linear scale; units of time; user-adjustable	Linear scale; units of time; user-adjustable	
Y-Axis	Linear scale or semi-log scale (for DSA); units of uV, uV ² , nW, Hz, s, % or none (depending on the selected EEG parameter); user adjustable scale	Linear scale or semi-log scale (for DSA); units of uV, uV ² , nW, Hz, s, % or none (depending on the selected EEG parameter); user adjustable scale	Linear scale or semi-log scale (for DSA); units of uV, uV ² , nW, Hz, s, % or none (depending on the selected EEG parameter); user adjustable scale	
User Adjustable Filters	High-cut and low-cut filters	Notch, high-cut, and low-cut filters	Notch, high-cut, and low-cut filters	
aEEG Parameter Available	Yes	Yes	Yes	
Notification Available	No	No	No	

	Component Monitoring System Primary Predicate K080217	Persyst 14 EEG Review and Analysis Software K182181	CNS Envision Subject Device K192572	Comments
Data Input	Optional EEG amplifier	EEG data only; user-selected channels	EEG data only; user-selected channels	
Data & Analysis Output	Graph	Graph	Graph	
X-Axis	Linear scale; units of time; user-adjustable	Linear scale; units of time; user-adjustable	Linear scale; units of time; user-adjustable	
Y-Axis	Semi-log scale; units of uV	Semi-log scale; units of uV	Semi-log scale; units of uV	
User Adjustable Filters	No	No	No	
Electrocardiography (ECG) Parameter Analysis Available	No – Raw data display <u>only</u>	No– Raw data display <u>only</u>	No – Raw data display <u>only</u>	
Notification Available	No	No	No	
Data Input	Optional EEG amplifier or external source device	External source device	CNS Monitor; K080217	
Data Output Format	Graph	Graph	Graph	
X-Axis	Linear scale; units of time; user-adjustable	Linear scale; units of time; user-adjustable	Linear scale; units of time; user-adjustable	
Y-Axis	Linear scale; units of mV; user adjustable scale	Linear scale; units of mV; user adjustable scale	Linear scale; units of mV; user adjustable scale	
User Adjustable Filters	No	No	No	
Electromyography (EMG) Parameter Analysis Available	No – Raw data display <u>only</u>	No – Raw data display <u>only</u>	No – Raw data display <u>only</u>	
Notification Available	No	No	No	
Data Input	Optional EEG amplifier or external source device	External source device	CNS Monitor; K080217	
Data Output Format	Graph	Graph	Graph	

	Component Monitoring System Primary Predicate K080217	Persyst 14 EEG Review and Analysis Software K182181	CNS Envision Subject Device K192572	Comments
X-Axis	Linear scale; units of time; user-adjustable	Linear scale; units of time; user-adjustable	Linear scale; units of time; user-adjustable	
Y-Axis	Linear scale; units of mV; user adjustable scale	Linear scale; units of mV; user adjustable scale	Linear scale; units of mV; user adjustable scale	
User Adjustable Filters	No	No	No	
Vital Signs Parameter Analysis Available	No – Raw data display <u>only</u>	No– Raw data display <u>only</u>	No – Raw data display <u>only</u>	
Notification Available	No	No	No	
Data Input	External source device	External source device	CNS Monitor; K080217	
Data Output Format	Graph	Graph	Graph	
X-Axis	Linear scale; units of time; user-adjustable	Linear scale; units of time; user-adjustable	Linear scale; units of time; user-adjustable	
Y-Axis	Linear scale; units based on selected vital sign; user adjustable scale	Linear scale; units based on selected vital sign; user adjustable scale	Linear scale; units based on selected vital sign; user adjustable scale	
User Adjustable Filters	No	No	No	
Intracranial Pressure (ICP) Parameter Analysis Available	No – Raw data display <u>only</u>	No– Raw data display <u>only</u>	No – Raw data display <u>only</u>	
Notification Available	No	No	No	
Data Input	External source device	External source device	CNS Monitor; K080217	
Data Output Format	Graph	Graph	Graph	
X-Axis	Linear scale; units of time; user-adjustable	Linear scale; units of time; user-adjustable	Linear scale; units of time; user-adjustable	
Y-Axis	Linear scale; units of mmHg, kPa, or cmH2O; user adjustable scale	Linear scale; units of mmHg, kPa, or cmH2O; user adjustable scale	Linear scale; units of mmHg, kPa, or cmH2O; user adjustable scale	
User Adjustable Filters	No	No	No	

	Component Monitoring System Primary Predicate K080217	Persyst 14 EEG Review and Analysis Software K182181	CNS Envision Subject Device K192572	Comments
Transcranial Doppler (TCD) Parameters Analysis Available	No – Raw data display <u>only</u>	No	No – Raw data display <u>only</u>	
Notification Available	No	N/A	No	
Data Input	External source device	N/A	CNS Monitor; K080217	
Data Output Format	Graph	N/A	Graph	
X-Axis	Linear scale; units of time; user-adjustable	N/A	Linear scale; units of time; user-adjustable	
Y-Axis	Linear scale; units based on selected TCD parameter; user adjustable scale	N/A	Linear scale; units based on selected TCD parameter; user adjustable scale	
User Adjustable Filters	No	N/A	No	
Glasgow Coma Score (GCS) Parameters Analysis Available	No – Raw data display <u>only</u>	No – Raw data display <u>only</u>	No – Raw data display <u>only</u>	
Notification Available	No	No	No	
Data Input	External source device	External source device	CNS Monitor; K080217	
Data Output Format	Graph	Graph	Graph	
X-Axis	Linear scale; units of time; user-adjustable	Linear scale; units of time; user-adjustable	Linear scale; units of time; user-adjustable	
Y-Axis	Linear scale; no units; user adjustable scale	Linear scale; no units; user adjustable scale	Linear scale; no units; user adjustable scale	
User Adjustable Filters	No	No	No	
Cardiac Output Parameters Analysis Available	No – Raw data display <u>only</u>	No	No – Raw data display <u>only</u>	
Notification Available	No	N/A	No	

	Component Monitoring System Primary Predicate K080217	Persyst 14 EEG Review and Analysis Software K182181	CNS Envision Subject Device K192572	Comments
Data Input	External source device	N/A	CNS Monitor; K080217	
Data Output Foramt	Graph	N/A	Graph	
X-Axis	Linear scale; units of time; user-adjustable	N/A	Linear scale; units of time; user-adjustable	
Y-Axis	Linear scale; units based on selected Cardiac Output parameter; user adjustable scale	N/A	Linear scale; units based on selected Cardiac Output parameter; user adjustable scale	
User Adjustable Filters	No	N/A	No	
Direct data collection from external source devices	Yes	No	No	The primary predicate device performs direct data collection from external source devices at the bedside. The subject device instead reads data collected by the CNS Monitor (K080217), similar to Persyst 14 (K182181).
Remote review	No	Yes	Yes	The CNS Monitor (K080217) is intended for bedside use, while the subject device is meant for care providers to review data remotely, similar to Persyst 14 (K182181).

	Component Monitoring System Primary Predicate K080217	Persyst 14 EEG Review and Analysis Software K182181	CNS Envision Subject Device K192572	Comments
Adjustable review speed	No	Yes	Yes	Unlike the CNS Monitor (K080217), the subject device offers adjustable review speed to meet the needs of remote review, similarly to Persyst 14 (K182181). This speed adjustment means that users can change the output using a low to high speed variable function bar to choose the pace at which to view the data measurement traces as part of the display.

**Electrical Safety and
Electromagnetic
Compatibility Testing:**

Not Applicable; Software-only

**Non-Clinical
Performance Testing:**

Software verification and validation testing was conducted and documentation provided as recommended by the Guidance for the Content of Software Contained in Medical Devices, issued May 2005. Traceability has been documented between all system specifications to validation test protocols. Verification and validation testing includes module-level testing, integration-level testing, and system-level testing.

In addition, tests according to “IEC 62366-1:2015, Medical Devices Part 1—Application of usability engineering to medical devices” were performed.

The software for this device is determined as a “moderate” level of concern because a failure or latent flaw could lead to a minor injury to the patient through incorrect information or through the action of the care provider.

Verification and validation activities established the safety and performance characteristics of the subject device with respect to the predicate device.

Conclusion:

Based on the intended use, technological characteristics as compared to predicates, and performance testing performed, the CNS Envision software is substantially equivalent to the Predicate Device.