



November 23, 2019

Cadwell Industries, Inc.
Emily Whitehead
Project Engineer
909 N. Kellogg Street
Kennewick, Washington 99336

Re: K190760
Trade/Device Name: Cadwell Bolt Software
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLT, OMA, ORT
Dated: October 22, 2019
Received: October 24, 2019

Dear Emily Whitehead:

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)

K190760

Device Name

Cadwell Bolt Software

Indications for Use (Describe)

1. Cadwell Bolt is a software-only device intended for post-hoc analysis of EEG data. This device is intended to be used by qualified medical practitioners who will exercise professional judgment in using the information. This device is intended to be used with EEG data from patients of all ages.

2. Cadwell Bolt includes the calculation and display of a set of quantitative measures intended to monitor and analyze the EEG data. These include the following 10 analyzers:

-Amplitude Integrated EEG (aEEG),

-Peak Envelope,

-Envelope Asymmetry,

-Spectrogram,

-Band Power,

-Power Ratio,

-Spectral Entropy,

-Burst Suppression Ratio,

-Inter-burst Interval, and

-Bursts-per-Minute.

These quantitative EEG measures should always be interpreted in conjunction with review of the original EEG data. A minimum of one epoch of data is required to perform Bolt analysis.

3. The aEEG functionality included in Cadwell Bolt is intended to monitor the state of the brain.

4. Cadwell Bolt can provide notifications, based on user-defined thresholds, for quantitative EEG measures such as a notification within the application software that can be used when processing a record during acquisition. Delays can occur between the beginning of an event and when the Bolt notification will be shown to a user. Cadwell Bolt notifications cannot be used as a substitute for real-time monitoring of the underlying EEG data by a trained expert.

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.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K190760

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: Cadwell Industries, Inc.
909 N. Kellogg Street
Kennewick, Washington 99336
509-735-6481

Contact Person: Emily Whitehead, Project Engineer
emilyw@cadwell.com

Date Prepared: November 22, 2019

Trade Name: Cadwell Bolt Software

Regulation Name: Electroencephalograph

Regulation Number: 21 CFR 882.1400

Regulatory Classification: Class II

Product Codes: OLT (Primary) non-normalizing quantitative electroencephalograph (EEG) software
ORT (secondary) burst suppression detection software for electroencephalograph
OMA amplitude-integrated electroencephalograph (aEEG)

Review Panel: Neurological and Physical Medicine Devices (OHT5)
Neurosurgical, Neurointerventional and Neurodiagnostic Devices (DHT5A)

Predicate Device: **K151929** Persyst 13 EEG Review and Analysis Software; Primary Predicate
K173366 NicoletOne; Secondary predicate
K161027 Cadwell Ampliscan; Secondary predicate

Device Description: Cadwell Bolt is a software-only device for use with EEG data. The Cadwell Bolt receives EEG data as an input and uses this input to calculate and display the following quantitative measures of electroencephalographic data:
(1) amplitude integrated EEG (aEEG),

- (2) peak envelope,
- (3) envelope asymmetry,
- (4) spectrogram,
- (5) band power,
- (6) power ratio,
- (7) spectral entropy,
- (8) burst suppression ratio,
- (9) inter-burst interval, and
- (10) bursts-per-minute.

In addition to the 10 analyzers mentioned above, Cadwell Bolt calculates if a value is greater than a user-defined threshold. A horizontal black bar is displayed in the trend window and signifies the current threshold setting. The user may move the bar up/down to adjust the threshold.

Thresholding is available for the following trends:

- peak envelope,
- envelope asymmetry,
- spectrogram,
- band power, and
- power ratio.

The Cadwell Bolt device performs analysis on a user-defined set of EEG channels within the EEG data and displays graphical results to be interpreted by qualified medical practitioners. Additional user-selectable parameters are available depending on the analyzer selected for display. These parameters include frequency ranges or bands for analysis, number of epochs to average, and minimum burst suppression durations. Using the user-defined thresholds, Cadwell Bolt can provide notifications to the user and can optionally highlight the associated EEG data. Notifications and/ or highlights can be accepted or rejected by a qualified medical practitioner. Additional features and user-selectable parameters include:

- Output display color
- Output display size
- Output display name
- Epoch length
- Notch filter
- Selected inputs (bipolar or referential)
- Output display time scale (y-axis)

Cadwell Bolt is intended to be used in conjunction with Cadwell Acquisition Software. The Cadwell Bolt device is for use by qualified medical practitioners and does not provide any diagnostic conclusions about the patient's condition to the user.

Intended Use:

The Cadwell Bolt Software is intended to be used for post-hoc analysis of EEG software to analyze 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 recordings 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 K151929 <i>Persyst 13 Software</i>	Subject Device K190760 <i>Cadwell Bolt</i>	Comments
1. Persyst 13 EEG Review and Analysis Software is intended for the review, monitoring and analysis of EEG recordings made by electroencephalogram (EEG) devices using scalp electrodes and 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 13 is intended to mark previously acquired sections of the adult (greater than or equal to 18 years old) 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	1. Cadwell Bolt is a software-only device intended for post-hoc analysis of EEG data. This device is intended to be used by qualified medical practitioners who will exercise professional judgment in using the information. This device is intended to be used with EEG data from patients of all ages. 2. Cadwell Bolt includes the calculation and display of a set of quantitative measures intended to monitor and analyze the EEG data. These include the following 10 analyzers: - Amplitude Integrated EEG (aEEG), - Peak Envelope, - Envelope Asymmetry, - Spectrogram, - Band Power, - Power Ratio, - Spectral Entropy, - Burst Suppression Ratio, - Inter-burst Interval, and	<i>The propose IFU is a subset of the predicate device. Quantitative measures are listed in the Cadwell Bolt indications for use (#2); Additional quantitative measures not included with K151929 are covered by the secondary predicate devices that were cleared in the same regulation for the same intended use.</i> <i>All newly proposed quantitative measures are verified against Cadwell internal requirements and validated to demonstrate substantial equivalence as compared to the predicate device implementation; the validation testing was submitted as part of this 510(k) submission. Both devices are prescription use only, are intended to be used with EEG data for post-hoc analysis, and are intended to be used by medical professionals. Neither Bolt nor the primary predicate device provide diagnostic conclusions to the user as part of the output.</i> <i>Wording differences appear for the sake of clarification purposes only. Differences in</i>

Primary Predicate K151929 Persyst 13 Software	Subject Device K190760 Cadwell Bolt	Comments
full scalp montage according to the standard 10/20 system. 3. The Spike Detection component of Persyst 13 is intended to mark previously acquired sections of the patient's EEG recordings that may correspond to spikes, in order to assist qualified clinical practitioners in the assessment of EEG traces. The Spike Detection component is intended to be used in patients at least one month old. Persyst 13 Spike Detection performance has not been assessed for intracranial recordings. 4. Persyst 13 includes the calculation and display of a set of quantitative measures intended to monitor and analyze the EEG waveform. These include FFT, Rhythmicity, Peak Envelope, Artifact Intensity, Amplitude, Relative Symmetry and Suppression Ratio. Automatic event marking is not applicable to the quantitative measures. These quantitative EEG measures should always be interpreted in conjunction with review of the original EEG waveforms. 5. The aEEG functionality included in Persyst 13 is intended to monitor the state of the brain. The automated event marking function of Persyst 13 is not applicable to aEEG. 6. Persyst 13 provides notifications for seizure detection, quantitative EEG and aEEG that can be used when processing a record during acquisition. These include an on screen display and the optional sending of an email message. Delays of up to several minutes can occur between the beginning of a seizure and when the Persyst 13 notifications will be shown to a user. Persyst 13 notifications cannot be used as a substitute for real time monitoring of the underlying EEG by a trained expert.	-Bursts-per-Minute. These quantitative EEG measures should always be interpreted in conjunction with review of the original EEG data. A minimum of one epoch of data is required to perform Bolt analysis. 3. The aEEG functionality included in Cadwell Bolt is intended to monitor the state of the brain. 4. Cadwell Bolt can provide notifications, based on user-defined thresholds, for quantitative EEG measures such as a notification within the application software that can be used when processing a record during acquisition. Delays can occur between the beginning of an event and when the Bolt notification will be shown to a user. Cadwell Bolt notifications cannot be used as a substitute for real-time monitoring of the underlying EEG data by a trained expert. 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.	<i>the IFUs between the subject and predicate devices do not change the intended use between the devices.</i>

Primary Predicate K151929 <i>Persyst 13 Software</i>	Subject Device K190760 <i>Cadwell Bolt</i>	<i>Comments</i>
7. Persyst AR (Artifact Reduction) is intended to reduce EMG, eye movement, and electrode artifacts in a standard 10-20 EEG recording. AR does not remove the entire artifact signal, and is not effective for other types of artifacts. AR may modify portions of waveforms representing cerebral activity. Waveforms must still be read by a qualified medical practitioner trained in recognizing artifact, and any interpretation or diagnosis must be made with reference to the original waveforms. This device does not provide any diagnostic conclusion about the patient's condition to the user.		

Substantial Equivalence

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

Device (Right) →	NicoletOne K173366	Persyst 13 EEG Review and Analysis Software Primary Predicate K151929	Cadwell Ampliscan K161027	Cadwell Bolt Subject Device K190760	Comments
Item of Comparison (Below)					
Physical State	Software-only	Software-only	Software-only	Software-only	Same
Device Class	Class II	Class II	Class II	Class II	Same
Class Name	EEG	EEG	EEG	EEG	Same
Classifying Regulation	882.1400	882.1400	882.1400	882.1400	Same
Intended User	Medical Professionals	Medical Professionals	Medical Professionals	Medical Professionals	Same
User Input	Mouse/Keyboard	Mouse/Keyboard	Mouse/Keyboard	Mouse/Keyboard	Same
Power	N/A	N/A	N/A	N/A	All devices are software-only and operate on a computer.
Amplitude-integrated EEG Trend					
Trend Available	Yes	Yes	Yes	Yes	Same
Notification Available	N/A	Yes	No	No	The predicate device offers notifications for the amplitude integrated EEG trend, whereas Bolt does not offer notifications for this specific trend. Page 2 of this

Device (Right) →	NicoletOne K173366	Persyst 13 EEG Review and Analysis Software Primary Predicate K151929	Cadwell Ampliscan K161027	Cadwell Bolt Subject Device K190760	Comments
Item of Comparison (Below)					Summary includes the notifications that are included with other analyzers. This feature is a convenience and is based on user-defined thresholds which are pre-set and lack of this feature does not affect the intended use of the device.
Amplitude-integrated EEG Trend					
Analysis Input	EEG data; user-selected channels	EEG data; user-selected channels	EEG data; user-selected channels	EEG data; user-selected channels	Same
Analysis Output	Graph	Graph; Over-threshold notification	Graph	Graph	Same
X-Axis	Linear scale; units of time; user-adjustable	Linear scale; units of time; user-adjustable	Linear scale; units of time; user-adjustable	Linear scale; units of time; user-adjustable	Same
Y-Axis	Semi-log scale; units of uV; user-adjustable	Semi-log scale; units of uV; fixed scale	Semi-log scale; units of uV; fixed scale	Semi-log scale; units of uV (microvolts); fixed scale	Same

Device (Right) →	NicoletOne K173366	Persyst 13 EEG Review and Analysis Software Primary Predicate K151929	Cadwell Ampliscan K161027	Cadwell Bolt Subject Device K190760	Comments
Item of Comparison (Below)					
User Adjustable Filters	High cut and low-cut filters	Notch, high-cut, and low-cut filters	Notch filter	Notch filter	Filtering is performed as a preliminary step, before the trend analysis. Lack of high and low-cut filters does not change the intended use and it does not raise different questions of safety and effectiveness as performance testing (validation of the analyzers) has been submitted to demonstrate substantial equivalence.
Power Ratio Trend					
Trend Available	No	Yes	No	Yes	-

Device (Right) →	NicoletOne K173366	Persyst 13 EEG Review and Analysis Software Primary Predicate K151929	Cadwell Ampliscan K161027	Cadwell Bolt Subject Device K190760	Comments
Item of Comparison (Below)					
Power Ratio Trend					
Notification Available	NA	Yes	-	Yes	Bolt notification consists of a yellow indicator adjacent to the trend. Optionally, Bolt notification highlights the EEG data for the duration that the trend is over-threshold. The predicate, K151929 Persyst 13, marks and displays notifications in the EEG data and can optionally send an email to the user if a trend is over-threshold. Although the notification

Device (Right) →	NicoletOne K173366	Persyst 13 EEG Review and Analysis Software Primary Predicate K151929	Cadwell Ampliscan K161027	Cadwell Bolt Subject Device K190760	Comments
Item of Comparison (Below)					
					methodology is slightly different, both the subject device and predicate device perform threshold notifications in a similar manner.
Power Ratio Trend					
Analysis Input	-	EEG data; user-selected channels	-	EEG data; user-selected channels	Same
Analysis Output	-	Graph; over-threshold notification	-	Graph; over-threshold notification	Same
X-Axis	-	Linear scale; units of time; user-adjustable	-	Linear scale; units of time; user-adjustable	Same
Y-Axis	-	Linear scale; numerical values; user-adjustable	-	Linear scale; numerical values; user-adjustable	Same
User Adjustable Filters	-	Notch, high cut, and low-cut filters	-	Notch filter only	Filtering is performed as a preliminary step, before the trend analysis. Lack of high and low-cut filters does not change the intended use and it does not raise different questions of safety and effectiveness as performance testing

Device (Right) →	NicoletOne K173366	Persyst 13 EEG Review and Analysis Software Primary Predicate K151929	Cadwell Ampliscan K161027	Cadwell Bolt Subject Device K190760	Comments
Item of Comparison (Below)					(validation of the analyzers) has been submitted to demonstrate substantial equivalence.
Band Power Trend					
Trend Available	Yes	Yes	No	Yes	-
Notification Available	NA	Yes	-	Yes	Bolt notification consists of a yellow indicator adjacent to the trend. Optionally, Bolt notification highlights the EEG data for the duration that the trend is over- threshold. The predicate, K151929 Persyst 13, marks and displays notifications in the EEG data and can optionally send an

Device (Right) →	NicoletOne K173366	Persyst 13 EEG Review and Analysis Software Primary Predicate K151929	Cadwell Ampliscan K161027	Cadwell Bolt Subject Device K190760	Comments
Item of Comparison (Below)					
					email to the user if a trend is over-threshold. Although the notification methodology is slightly different, both the subject device and predicate device perform threshold notifications in a similar manner.
Band Power Trend					
Analysis Input	EEG data; user-selected channels	EEG data; user-selected channels	-	EEG data; user-selected channels	Same
Analysis Output	Graph	Graph; over-threshold notification	-	Graph; over-threshold notification	Same
X-Axis	Linear scale; units of time; user-adjustable	Linear scale; units of time; user-adjustable	-	Linear scale; units of time; user-adjustable	Same
Y-Axis	Linear or Log scale; units of percent; user-adjustable	Linear scale; numerical values; user-adjustable	-	Linear scale; units of percent; user-adjustable	Same
User Adjustable Filters	High cut and low-cut filters	Notch, high cut, and low-cut filters	-	Notch filter	Filtering is performed as a preliminary step, before the trend analysis. Lack of high and low-cut filters does not change the

Device (Right) →	NicoletOne K173366	Persyst 13 EEG Review and Analysis Software Primary Predicate K151929	Cadwell Ampliscan K161027	Cadwell Bolt Subject Device K190760	Comments
Item of Comparison (Below)					intended use and it does not raise different questions of safety and effectiveness as performance testing (validation of the analyzers) has been submitted to demonstrate substantial equivalence.
Spectrogram Trend					
Trend Available	Yes	Yes	No	Yes	-
Notification Available	NA	No	-	Yes	The predicate device offers notifications for the amplitude integrated EEG trend, whereas Bolt does not offer notifications for this specific trend. Page 2 of this Summary includes the notifications that are included with other analyzers. This feature is a convenience and is based on user-defined thresholds which are

Device (Right) →	NicoletOne K173366	Persyst 13 EEG Review and Analysis Software Primary Predicate K151929	Cadwell Ampliscan K161027	Cadwell Bolt Subject Device K190760	Comments
Item of Comparison (Below)					
					pre-set and lack of this feature does not affect the intended use of the device.
Analysis Input	EEG data; user-selected channels	EEG data; user-selected channels	-	EEG data; user-selected channels	Same
Analysis Output	Graph	Graph	-	Graph; over-threshold notification	Additional notification output is available in Bolt. This option is made available for users' preference and does not affect the primary analysis output which is similar between the subject and predicate devices.
X-Axis	Linear scale; units of time; user-adjustable	Linear scale; units of time; user-adjustable	-	Linear scale; units of time; user-adjustable	Same
<i>Spectrogram Trend</i>					
Y-Axis	Linear or Log scale; user-adjustable	Linear scale; units of Hz; user-adjustable	-	Linear scale; units of Hz; user-adjustable	Same

Device (Right) →	NicoletOne K173366	Persyst 13 EEG Review and Analysis Software Primary Predicate K151929	Cadwell Ampliscan K161027	Cadwell Bolt Subject Device K190760	Comments
Item of Comparison (Below)					
User Adjustable Filters	High cut and low-cut filters	Notch, high cut, and low-cut filters	-	Notch filter	Filtering is performed as a preliminary step, before the trend analysis. Lack of high and low-cut filters does not change the intended use and it does not raise different questions of safety and effectiveness as performance testing (validation of the analyzers) has been submitted to demonstrate substantial equivalence.
Spectral Entropy Trend					
Trend Available	Yes	No	No	Yes	-
Notification Available	NA	-	-	No	Same
Analysis Input	EEG data; user- selected channels	-	-	EEG data; user- selected channels	Same
Analysis Output	Graph; numerical value	-	-	Graph; numerical entropy value	Same
X-Axis	Linear scale; units of time; user-adjustable	-	-	Linear scale; units of time; user-adjustable	Same

Device (Right) →	NicoletOne K173366	Persyst 13 EEG Review and Analysis Software Primary Predicate K151929	Cadwell Ampliscan K161027	Cadwell Bolt Subject Device K190760	Comments
Item of Comparison (Below)					
<i>Spectral Entropy Trend</i>					
Y-Axis	Linear or Log scale; units of entropy; user- adjustable	-	-	Linear scale; units of entropy (1-100); fixed scale	Same
User Adjustable Filters	High cut and low-cut filters	-	-	Notch filter	Filtering is performed as a preliminary step, before the trend analysis. Lack of notch filter with respect to the secondary predicate, NicoletOne K173366, predicate does not change the intended use and it does not raise different questions of safety and effectiveness as performance testing (validation of the analyzers) has been submitted to

Device (Right) →	NicoletOne K173366	Persyst 13 EEG Review and Analysis Software Primary Predicate K151929	Cadwell Ampliscan K161027	Cadwell Bolt Subject Device K190760	Comments
Item of Comparison (Below)					
					demonstrate substantial equivalence.
Peak Envelope Trend					
Trend Available	Yes	Yes	No	Yes	-
Notification Available	NA	Yes	-	Yes	Bolt notification consists of a yellow indicator adjacent to the trend. Optionally, Bolt notification highlights the EEG data for the duration that the trend is over- threshold. The predicate, K151929 Persyst 13, marks and displays notifications in the EEG data and can optionally send an email to the user if a trend is over-threshold. Although the notification methodology is slightly different, both the subject device and predicate device perform threshold

Device (Right) →	NicoletOne K173366	Persyst 13 EEG Review and Analysis Software Primary Predicate K151929	Cadwell Ampliscan K161027	Cadwell Bolt Subject Device K190760	Comments
Item of Comparison (Below)					
					notifications in a similar manner.
Peak Envelope Trend					
Analysis Input	EEG data; user-selected channels	EEG data; user-selected channels	-	EEG data; user-selected channels	Same
Analysis Output	Graph	Graph; over-threshold notification	-	Graph; over-threshold notification	Same
X-Axis	Linear scale; units of time; user-adjustable	Linear scale; units of time; user-adjustable	-	Linear scale; units of time; user-adjustable	Same
Y-Axis	Linear or Log scale; units of uV; user-adjustable	Linear scale; units of uV; user-adjustable	-	Linear scale; units of uV; user-adjustable	Same
User Adjustable Filters	High cut and low cut filters	Notch, high cut, and low cut filters	-	Notch filter	Filtering is performed as a preliminary step, before the trend analysis. Lack of high and low-cut filters does not change the intended use and it does not raise different questions of safety and effectiveness as performance testing (validation of the analyzers) has been

Device (Right) →	NicoletOne K173366	Persyst 13 EEG Review and Analysis Software Primary Predicate K151929	Cadwell Ampliscan K161027	Cadwell Bolt Subject Device K190760	Comments
Item of Comparison (Below)					
					submitted to demonstrate substantial equivalence.
Asymmetry Trend					
Trend Available	No	Yes	No	Yes	-
Asymmetry Trend					
Notification Available	-	Yes	-	Yes	Same
Analysis Input	-	EEG data; user- selected channels restricted to homologous inputs	-	EEG data; user- selected channels restricted to homologous inputs	Same
Analysis Output	-	Graph; over-threshold notification	-	Graph; over-threshold notification	Same
X-Axis	-	Linear scale; units of time; user-adjustable	-	Linear scale; units of time; user-adjustable	Same
Y-Axis	-	Linear scale; units of percent; user- adjustable	-	Linear scale; units of percent; user- adjustable	Same
User Adjustable Filters	-	Notch, high cut, and low cut filters	-	Notch filter	Filtering is performed as a preliminary step, before the trend analysis. Lack of high and low-cut filters does

Device (Right) →	NicoletOne K173366	Persyst 13 EEG Review and Analysis Software Primary Predicate K151929	Cadwell Ampliscan K161027	Cadwell Bolt Subject Device K190760	Comments
Item of Comparison (Below)					
					not change the intended use and it does not raise different questions of safety and effectiveness as performance testing (validation of the analyzers) has been submitted to demonstrate substantial equivalence.
Burst Suppression Ratio					
Trend Available	Yes	No	No	Yes	-
Notification Available	No	-	-	No	Same
Analysis Input	EEG data; user-selected channels	-	-	EEG data; user-selected channels	Same
Analysis Output	Graph and numerical value	-	-	Graph and numerical value	Same
X-Axis	Linear scale; units of time; user-adjustable	-	-	Linear scale; units of time; user-adjustable	Same
Y-Axis	Linear scale; units of percent; user-adjustable	-	-	Linear scale; units of percent; fixed scale	Same
User Adjustable Filters	High-cut and low-cut filters	-	-	Notch filter	Filtering is performed as a preliminary step, before the trend

Device (Right) →	NicoletOne K173366	Persyst 13 EEG Review and Analysis Software Primary Predicate K151929	Cadwell Ampliscan K161027	Cadwell Bolt Subject Device K190760	Comments
Item of Comparison (Below)					analysis. Lack of high and low-cut filters does not change the intended use and it does not raise different questions of safety and effectiveness as performance testing (validation of the analyzers) has been submitted to demonstrate substantial equivalence.
<i>Inter-burst Interval</i>					
Trend Available	Yes	No	No	Yes	-
<i>Inter-burst Interval</i>					
Notification Available	No	-	-	No	Same
Analysis Input	EEG data; user-selected channels	-	-	EEG data; user-selected channels	Same
Analysis Output	Graph and numerical value	-	-	Graph and numerical value	Same
X-Axis	Linear scale; units of time; user-adjustable	-	-	Linear scale; units of time; user-adjustable	Same

Device (Right) →	NicoletOne K173366	Persyst 13 EEG Review and Analysis Software Primary Predicate K151929	Cadwell Ampliscan K161027	Cadwell Bolt Subject Device K190760	Comments
Item of Comparison (Below)					
Y-Axis	Linear scale; units of time; user-adjustable	-	-	Linear scale; units of time; user-adjustable	Same
User Adjustable Filters	High-cut and low-cut filters	-	-	Notch filter	Filtering is performed as a preliminary step, before the trend analysis. Lack of high and low-cut filters does not change the intended use and it does not raise different questions of safety and effectiveness as performance testing (validation of the analyzers) has been submitted to demonstrate substantial equivalence.
Bursts-per-Minute					
Trend Available	Yes	No	No	Yes	Same
Notification Available	No	-	-	No	Same
Analysis Input	EEG data; user- selected channels	-	-	EEG data; user- selected channels	Same

Device (Right) →	NicoletOne K173366	Persyst 13 EEG Review and Analysis Software Primary Predicate K151929	Cadwell Ampliscan K161027	Cadwell Bolt Subject Device K190760	Comments
Item of Comparison (Below)					
Analysis Output	Graph and numerical value	-	-	Graph and numerical value	Same
X-Axis	Linear scale; units of time; user-adjustable	-	-	Linear scale; units of time; user-adjustable	Same
Y-Axis	Linear scale; units of # of bursts; user- adjustable	-	-	Linear scale; units of # of bursts; user- adjustable	Same
User Adjustable Filters	High-cut and low-cut filters	-	-	Notch filter	Filtering is performed as a preliminary step, before the trend analysis. Lack of high and low-cut filters does not change the intended use and it does not raise different questions of safety and effectiveness as performance testing (validation of the analyzers) has been submitted to demonstrate substantial equivalence.

**Electrical Safety and
Electromagnetic
Compatibility Testing:**

Not Applicable; Software-only

**Non-Clinical
Performance Testing:**

The Cadwell Bolt Software was tested for performance in accordance with internal requirements. Additionally, software verification and validation were performed to test the implementation of the Bolt analyzers and the overall function of Bolt software. Overall implementation of Bolt measures was tested by analyzing known arbitrary EEG data and confirming that the expected output was obtained. By these results, the Cadwell Bolt Software meets predetermined requirements for the 10 analyzers proposed in this 510(k).

Cadwell Bolt Software implements public domain (non-proprietary) quantitative analysis measures that are identical or similar to the predicate devices identified in this submission. Arbitrary data of known value was input, and results were compared for each Cadwell Bolt Software analyzer proposed in this 510(k) and each predicate which has been identified as containing the analyzer to demonstrate substantial equivalence. The results were similar in morphology and magnitude for each measure, the pre-specified criteria necessary to demonstrate adequate performance. Minor differences were observed in the trend outputs, but these subtle differences were due to smoothing and graphical display; they do not affect overall morphology of the output. Therefore, given the identical inputs and adequately similar outputs, the performance data are adequate to demonstrate that the proposed Cadwell Bolt Software is substantially equivalent to the identified predicate analyzers.

Additional analysis of the results included the following: the graphical outputs from Bolt and the predicate devices were quantified and a correlation coefficient was calculated between the two device outputs. For trends with a quantitative output displayed to the user, percent difference was also calculated. The percent difference calculation provides comparisons of amplitudes while the correlation coefficient provides comparison of morphology.

Correlation values greater than 0.80 and percent difference values less than 10% were considered to be substantially equivalent. Known/generated inputs were analyzed for applicable trends and all correlation values were greater than or equal to 0.900. Quantitative analysis was also performed on sample EEG data at various time scales and with various montages and/or frequency bands. These results are summarized in the tables to follow:

Peak Envelope

	<i>15-minute</i>	<i>1-hour</i>	<i>4-hour</i>	<i>8-hour</i>
<i>All 10/20</i>	.951	.917	.913	.896
<i>Left Hemi</i>	.933	.933	.931	.879
<i>Right Hemi</i>	.949	.946	.911	.898

Envelope Asymmetry

	<i>15-minute</i>	<i>1-hour</i>	<i>4-hour</i>	<i>8-hour</i>
<i>6-14Hz</i>	.909	.859	.857	.819
<i>2-18Hz</i>	.913	.857	.850	.817

Spectrogram

	<i>15-minute</i>	<i>1-hour</i>	<i>4-hour</i>	<i>8-hour</i>
<i>All 10/20</i>	.938	.969	.825	.852
<i>Left Hemi</i>	.934	.958	.826	.851
<i>Right Hemi</i>	.969	.947	.848	.852

Band Power

	<i>15-minute</i>	<i>1-hour</i>	<i>4-hour</i>	<i>8-hour</i>
<i>All 10/20 7-12Hz</i>	.955	.898	.874	.891
<i>Right Hemi 8-13Hz</i>	.935	.870	.890	.857
<i>Left Hemi 8-13Hz</i>	.939	.901	.894	.892
<i>Right Hemi 13-20Hz</i>	.944	.910	.915	.917
<i>Left Hemi 13-20Hz</i>	.927	.897	.929	.933

Power Ratio

	<i>15-minute</i>	<i>1-hour</i>	<i>4-hour</i>	<i>8-hour</i>
<i>All 10/20</i>	.938	.923	.902	.867
<i>Left Hemi</i>	.966	.914	.845	.850
<i>Right Hemi</i>	.896	.902	.843	.850

Spectral Entropy

	<i>15-minute</i>	<i>1-hour</i>	<i>4-hour</i>	<i>8-hour</i>
<i>Correlation</i>	.957	.961	.998	.972

<i>Percent Difference</i>	5.3	3.4	8.7	7.2
----------------------------------	-----	-----	-----	-----

Burst Suppression

	<i>IBI</i>	<i>BSR</i>	<i>BPM</i>
<i>Correlation</i>	0.992	0.999	0.999
<i>Percent Difference</i>	1.25	1.37	1.94

The resulting correlation coefficients and percent differences supported the determination of substantial equivalence.

Conclusion:

Verification and validation activities were performed to demonstrate that the Cadwell Bolt Software is substantially equivalent to the predicate device.