



May 18, 2020

Natus Medical Incorporated DBA Excel-Tech Ltd. (XLTEK)
Sanjay Mehta
Director, Global Regulatory Affairs
2568 Bristol Circle
Oakville, Ontario L6H 5S1
Canada

Re: K200878

Trade/Device Name: Natus NeuroWorks
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMB, OMA, OLT
Dated: April 1, 2020
Received: April 2, 2020

Dear Sanjay Mehta:

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,

for
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)

Device Name
Natus NeuroWorks

Indications for Use (Describe)

Natus NeuroWorks is EEG software that displays physiological signals. The intended user of this product is a qualified medical practitioner trained in Electroencephalography who will exercise professional judgment in using the information. The NeuroWorks EEG software allows acquisition, display, archive, review and analysis of physiological signals.

- The Seizure Detection component of NeuroWorks 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 full scalp montage according to the standard 10/20 system.
- The Spike Detection component of NeuroWorks is intended to mark previously acquired sections of the adult (greater than or equal to 18 years) EEG recordings that may correspond to electrographic spikes, in order to assist qualified clinical practitioners in the assessment of EEG traces. EEG recordings should be obtained with full scalp montage according to the standard 10/20 system.
- aEEG, Burst Suppression, Envelope, Alpha variability, Spectral Edge and Spectral Entropy trending functionalities included in NeuroWorks are intended to assist the user while monitoring the state of the brain. The automated event marking function of Neuroworks is not applicable to these analysis features.
- NeuroWorks also includes the display of a quantitative EEG plot, Density Spectral Array (DSA), which is intended to help the user to monitor and analyze the EEG waveform. The automated event marking function of NeuroWorks is not applicable to DSA.
- 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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510(k) SUMMARY

Submission Date: 25 April 2020

Submitter: Natus Medical Incorporated DBA Excel-Tech Ltd. (XLTEK)
2568 Bristol Circle
Oakville, Ontario, L6H 5S1
Canada

Submitter and Application Correspondent: Mr. Sanjay Mehta
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Manufacturing Site: Natus Medical Incorporated DBA Excel-Tech Ltd. (XLTEK)
2568 Bristol Circle
Oakville, Ontario, L6H 5S1
Canada

Trade Name: Natus NeuroWorks

Common and Classification Name: Electroencephalograph

Classification Regulation: 21 CFR §882.1400

Product Code: OMB (primary), OMA, OLT

<i>Substantially Equivalent Devices:</i>	<i>New Model</i>	<i>Predicate 510(k) Number</i>	<i>Predicate Manufacturer / Model</i>
	Natus NeuroWorks	K180421	Natus Medical Incorporated DBA Excel-Tech Ltd. (XLTEK) 2568 Bristol Circle Oakville, Ontario, L6H 5S1 Canada
	NicoletOne	K173366	Natus Neurology Inc.
	Moberg CNS	K080217	Moberg.

Device Description: Natus NeuroWorks is electroencephalography (EEG) software that displays physiological signals. The software platform is designed to work with Xltek and other select Natus amplifiers (headboxes). Software add-ons and optional accessories let you customize your system to meet your specific clinical EEG monitoring needs.

Intended Use: Natus NeuroWorks is EEG software that displays physiological signals. The intended user of this product is a qualified medical practitioner trained in Electroencephalography who will exercise professional judgment in using the information.

The Natus NeuroWorks EEG software allows acquisition, display, archive, review and analysis of physiological signals.

- The Seizure Detection component of Natus NeuroWorks 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 full scalp montage according to the standard 10/20 system.
- The Spike Detection component of Natus NeuroWorks is intended to mark previously acquired sections of the adult (greater than or equal to 18 years) EEG recordings that may correspond to electrographic spikes, in order to assist qualified clinical practitioners in the assessment of EEG traces. EEG recordings should be obtained with full scalp montage according to the standard 10/20 system.
- aEEG, Burst Suppression, Envelope, Alpha variability, Spectral Edge and Spectral Entropy trending functionalities included in Natus NeuroWorks are intended to assist the user while monitoring the state of the brain. The automated event marking function of Natus NeuroWorks is not applicable to these analysis

features.

- Natus NeuroWorks also includes the display of a quantitative EEG plot, Density Spectral Array (DSA), which is intended to help the user to monitor and analyze the EEG waveform. The automated event marking function of Natus NeuroWorks is not applicable to DSA.
- This device does not provide any diagnostic conclusion about the patient’s condition to the user.

Comparison to Predicate Devices:

The Natus NeuroWorks software application is being compared to the software applications in the predicates NeuroWorks software (K180421) NicoletOne (K173366) and Moberg CNS (K080217). These software applications acquire, display, store, and archive electroencephalographic signals from the brain and other signals (such as electromyography, respiratory and/or oxygen saturations) for Electroencephalographic and/or Polysomnographic recordings. These devices also allow onscreen review, user-controlled annotation and user-controlled marking of data and generating summary reports.

The following table provides a substantial equivalence comparison of the Natus NeuroWorks software application under review to the three predicate devices.

Table 1: Substantial Equivalence, Trends and other features					
Feature	Predicate	Predicate	<u>Primary</u> Predicate	Subject Device	Comments
	<i>NicoletOne K173366</i>	<i>Moberg CNS K080217</i>	<i>Natus NeuroWorks K180421</i>	<i>Natus NeuroWorks</i>	
Device Class	Class II	Class II	Class II	Class II	Identical
Class Name	EEG	EEG	EEG	EEG	Identical
Classifying Regulation (Primary)	882.1400	882.1400	882.1400	882.1400	Identical
Intended User	Medical Professional	Medical Professional	Medical Professional	Medical Professional	Identical

Table 1: Substantial Equivalence, Trends and other features

Feature	Predicate	Predicate	Primary Predicate	Subject Device	Comments
	<i>NicoletOne K173366</i>	<i>Moberg CNS K080217</i>	<i>Natus NeuroWorks K180421</i>	<i>Natus NeuroWorks</i>	
Indications for Use	<p>The NicoletOne EEG/PSG software performs recording, displaying, analysis, printing and storage of physiological signals to assist in the diagnosis of various neurological disorders, sleep disorders and sleep related respiratory disorders. It is intended to monitor the state of the brain by recording and displaying EEG signals and can receive and display a variety of third party signals such as ECG, EMG, Oxygen Saturation or Respiration for patients of all ages.</p> <p>NicoletOne software allows:</p>	<p>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 monitoring devices (such as ICP, ECG, SpO2, and others). It also has the optional capability to record and display patient video.</p> <p>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</p>	<p>The Natus NeuroWorks is EEG software that displays physiological signals. The intended User of this product is a qualified medical practitioner trained in Electroencephalography. This device is intended to be used by qualified medical practitioners who will exercise professional judgment in using the information.</p> <ul style="list-style-type: none"> - The Natus NeuroWorks EEG software allows acquisition, display, archive, review and analysis of physiological signals. - The Seizure Detection component of Natus NeuroWorks is intended to mark previously acquired sections of the adult (greater than or equal to 18 years) EEG recordings that may correspond to electrographic 	<p>The Natus NeuroWorks is EEG software that displays physiological signals. The intended User of this product is a qualified medical practitioner trained in Electroencephalography. This device is intended to be used by qualified medical practitioners who will exercise professional judgment in using the information.</p> <ul style="list-style-type: none"> - The Natus NeuroWorks EEG software allows acquisition, display, archive, review and analysis of physiological signals. - The Seizure Detection component of Natus NeuroWorks 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 full scalp montage 	<p>Equivalent, for the following reasons:</p> <ul style="list-style-type: none"> - Natus NeuroWorks 9.2 intended use is the same as Primary predicate and “NicoletOne” predicate devices. - Nicolet One and Moberg CNS and Natus NeuroWorks all permit the recording of EEG data from corresponding EEG amplifiers. - Nicolet One and Moberg CNS and Natus NeuroWorks all permit the receipt of data from various third party physiological monitoring devices utilizing the same hardware ports these devices provide to output data to external recording systems such as Nicolet One, Moberg EEG, and Natus NeuroWorks software.

Table 1: Substantial Equivalence, Trends and other features

Feature	Predicate	Predicate	<u>Primary</u> Predicate	Subject Device	Comments
	<i>NicoletOne K173366</i>	<i>Moberg CNS K080217</i>	<i>Natus NeuroWorks K180421</i>	<i>Natus NeuroWorks</i>	
	<ul style="list-style-type: none"> - Automated analysis of physiological signals that is intended for use only in adults. - An optional Audio/visual alert for user defined threshold on calibrated DC input. These alerts are not intended for use as life support such as vital signs monitoring or continuous medical surveillance in intensive care units. - Sleep report templates are provided which summarize recorded and scored sleep data using simple measures including count, average, maximum and minimum values 	clinical research settings.	<ul style="list-style-type: none"> seizures, in order to assist qualified clinical practitioners in the assessment of EEG traces. EEG recordings should be obtained with full scalp montage according to the standard 10/20 system. - The Spike Detection component of Natus NeuroWorks is intended to mark previously acquired sections of the adult (greater than or equal to 18 years) EEG recordings that may correspond to electrographic spikes, in order to assist qualified clinical practitioners in the assessment of EEG traces. EEG recordings should be obtained with full scalp montage according to the standard 10/20 system. - The aEEG functionality 	<ul style="list-style-type: none"> according to the standard 10/20 system. - The Spike Detection component of Natus NeuroWorks is intended to mark previously acquired sections of the adult (greater than or equal to 18 years) EEG recordings that may correspond to electrographic spikes, in order to assist qualified clinical practitioners in the assessment of EEG traces. EEG recordings should be obtained with full scalp montage according to the standard 10/20 system. - aEEG, Burst Suppression, Envelope, Alpha variability, Spectral Edge and Spectral Entropy trending functionalities included in Natus NeuroWorks are intended to assist the user while monitoring the state of the brain. The automated event marking function of Natus NeuroWorks is not applicable to these analysis features. 	

Table 1: Substantial Equivalence, Trends and other features

Feature	Predicate	Predicate	Primary Predicate	Subject Device	Comments
	<i>NicoletOne K173366</i>	<i>Moberg CNS K080217</i>	<i>Natus NeuroWorks K180421</i>	<i>Natus NeuroWorks</i>	
	<p>as well as data ranges for trended values.</p> <p>This device does not provide any diagnostic conclusion about the patient's condition and is intended to be used only by qualified and trained medical practitioners, in research and clinical environments.</p>		<p>included in Natus NeuroWorks is intended to monitor the state of the brain. The automated event marking function of Natus NeuroWorks is not applicable to aEEG.</p> <ul style="list-style-type: none"> - Natus NeuroWorks also includes the display of a quantitative EEG plot, Compressed Spectrum Array (CSA), which is intended to help the user to monitor and analyze the EEG waveform. The automated event marking function of Natus NeuroWorks is not applicable to CSA. <p>This device does not provide any diagnostic conclusion about the patient's condition to the user.</p>	<ul style="list-style-type: none"> - Natus NeuroWorks also includes the display of a quantitative EEG plot, Density Spectral Array (DSA), which is intended to help the user to monitor and analyze the EEG waveform. The automated event marking function of Natus NeuroWorks is not applicable to DSA. - This device does not provide any diagnostic conclusion about the patient's condition to the user. 	
User input	Mouse/keyboard	Mouse/keyboard	Mouse/keyboard	Mouse/keyboard	Same
Acquire, display, store,	Yes	Yes	Yes	Yes	Same

Table 1: Substantial Equivalence, Trends and other features

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	<i>NicoletOne K173366</i>	<i>Moberg CNS K080217</i>	<i>Natus NeuroWorks K180421</i>	<i>Natus NeuroWorks</i>	
and archive EEG/PSG and data from 3 rd party physiological monitoring devices					
Signal digitized	By separate proprietary amplifier	Amplifier included as part of the system	By separate proprietary amplifier	By separate proprietary amplifier	Equivalent
Third party pass-through inputs	Yes SaO2, heart rate	Yes SaO2, heart rate, RsO2	Yes Nonin Oximeter pass-through for Oxymetry, HR, and Pulse Wave	Yes Nonin Oximeter pass-through for Oxymetry, HR, and Pulse Wave	Equivalent
Power	NA	NA	NA	NA	Software operating on a computer.
EEG Software Detectors					
Spike Detection	Yes (Manual & Computer Assisted)	Yes (Manual)	Yes (Manual & Computer Assisted)	Yes (Manual & Computer Assisted)	Same or better: Natus NeuroWorks supports manual and automatic detection like in NicoletOne predicate device. The Moberg predicate device only allows for Manual detection.
Seizure Detection	Yes (Manual & Computer Assisted)	Yes (Manual)	Yes (Manual & Computer Assisted)	Yes (Manual & Computer Assisted)	
Burst Suppression	Yes	Yes	No	Yes	Equivalent:

Table 1: Substantial Equivalence, Trends and other features

Feature	Predicate	Predicate	Primary Predicate	Subject Device	Comments
	<i>NicoletOne K173366</i>	<i>Moberg CNS K080217</i>	<i>Natus NeuroWorks K180421</i>	<i>Natus NeuroWorks</i>	
					Feature added to Natus NeuroWorks Subject device. With this implementation the Natus NeuroWorks Subject device is now equivalent to NicoletOne and Moberg Predicate devices.
Amplitude Integrated EEG (aEEG)	Yes	Yes	Yes	Yes	Same
Power Spectrum	Yes	Yes	Yes	Yes	Same
Envelope Trend	Yes	No	No	Yes	Equivalent: Feature added to Natus NeuroWorks Subject device. With this implementation the Natus NeuroWorks Subject device is now equivalent to NicoletOne Predicate devices.
Total Power Trend	Yes	Yes	Yes	Yes	Same
Band Power Trend	Yes	Yes	Yes	Yes	Same
DSA / Spectrogram	Yes	Yes	Yes	Yes	Equivalent: The feature was already available in Natus NeuroWorks primary predicate device but named "CSA". This feature is now called DSA which is a more commonly used name. In addition to the old color scale from the CSA plot in previous Natus NeuroWorks versions, additional color scales were taken over from "NicoletOne" predicate device. It

Table 1: Substantial Equivalence, Trends and other features

Feature	Predicate	Predicate	<u>Primary</u> Predicate	Subject Device	Comments
	<i>NicoletOne K173366</i>	<i>Moberg CNS K080217</i>	<i>Natus NeuroWorks K180421</i>	<i>Natus NeuroWorks</i>	
					<p>provides better contrast improving the performance of the feature. Spectral resolution of 30Hz in Natus NeuroWorks 9.1 is improved in Natus NeuroWorks 9.2 to 64Hz (steps of 0.5Hz).</p> <p>To summarize: DSA trend plots in Natus NeuroWorks Subject device do not introduce a new trend feature, but in terms of performance it is now equivalent to NicoletOne predicate device where it was named "Spectrogram".</p>
Spectral edge/Median freq. Trends	Yes	Yes	No	Yes	<p>Equivalent:</p> <p>Feature added to Natus NeuroWorks Subject device. With this implementation the Natus NeuroWorks Subject device is now equivalent to NicoletOne and Moberg Predicate devices.</p>
Peak Frequency Trend	Yes	Yes	No	No	<p>This feature is not implemented in Natus NeuroWorks subject device because it is rarely used.</p>
Spectral Entropy trend	Yes	Yes	No	Yes	<p>Equivalent:</p> <p>Feature added to Natus NeuroWorks Subject device. With this implementation the Natus NeuroWorks Subject device is now equivalent to NicoletOne and Moberg Predicate devices.</p>

Table 1: Substantial Equivalence, Trends and other features

Feature	Predicate	Predicate	<u>Primary</u> Predicate	Subject Device	Comments
	<i>NicoletOne K173366</i>	<i>Moberg CNS K080217</i>	<i>Natus NeuroWorks K180421</i>	<i>Natus NeuroWorks</i>	
Frequency Ratio Trend	Yes	No	Yes	Yes	Equivalent
Alpha Variation Trend	Yes	Yes	No	Yes	Equivalent: Feature added to Natus NeuroWorks Subject device. With this implementation the Natus NeuroWorks Subject device is now equivalent to NicoletOne and Moberg Predicate devices.
Heart Rate data trend & summary	Yes	Yes	Yes	Yes	Same
R-R interval trend	Yes	No	No	Yes	Equivalent: Feature added to Natus NeuroWorks Subject device. With this implementation the Natus NeuroWorks Subject device is now equivalent to NicoletOne Predicate devices.
Other features					
Synchronized patient video	Yes	Yes	Yes	Yes	Same
Oximetry data display and reporting	Yes	Yes	Yes	Yes	Same

Table 1: Substantial Equivalence, Trends and other features

Feature	Predicate	Predicate	Primary Predicate	Subject Device	Comments
	<i>NicoletOne K173366</i>	<i>Moberg CNS K080217</i>	<i>Natus NeuroWorks K180421</i>	<i>Natus NeuroWorks</i>	
Data storage	Local or remote, hard disk	Local or remote, hard disk	Local or remote, hard disk	Local or remote, hard disk	Same
Audio/ Visual Alerts On Calibrated Channels	Yes	Yes	Yes	Yes	Same
Signals recorded (output)	Respiratory Effort (abdomen and chest) Airflow Pressure Snore Body Position Pulse Rate Pulse Rate Oximeter ECG ECG EEG EMG EMG EOG DC Leg Movement and other signals required for sleep studies	Respiratory Effort (abdomen and chest) Airflow Pressure Snore Body Position Pulse Rate Oximeter ECG EEG EMG EOG DC Leg Movement and other signals required for sleep studies	Respiratory Effort (abdomen and chest) Airflow Pressure Snore Body Position Pulse Rate Oximeter ECG EEG EMG EOG DC Leg Movement	Respiratory Effort (abdomen and chest) Airflow Pressure Snore Body Position Pulse Rate Oximeter ECG EEG EMG EMG EOG DC Leg Movement	Equivalent
Signals recorded (output) from 3 rd party physiological	SpO2 - Peripheral Capillary Oxygen Saturation T - Temperature	Oxygen Saturation, Pulse Rate, Temperature, Respiratory Rate,	Same	Same	Equivalent

Table 1: Substantial Equivalence, Trends and other features

Feature	Predicate	Predicate	Primary Predicate	Subject Device	Comments
	<i>NicoletOne K173366</i>	<i>Moberg CNS K080217</i>	<i>Natus NeuroWorks K180421</i>	<i>Natus NeuroWorks</i>	
monitoring devices	HR - Heart Rate NIBPS - Non-Invasive Blood Pressure Systolic NIPBD - Non-Invasive Blood Pressure Dystolic	Heart Rate, Non-Invasive Blood Pressure Systolic, Non-Invasive Blood Pressure Dystolic, Non-Invasive Blood Pressure Mean, Invasive Blood Pressure Systolic, Invasive Blood Pressure Dystolic, Invasive Blood Pressure Mean, Blood Flow Perfusion, Brain & Tissue Oxygenation, Intracranial Pressure			
Report generation including counts indexes, max / min/ average/ duration, range based data summaries.	Yes, customizable templates	Yes, customizable templates	Yes, customizable templates	Yes, customizable templates	Same

Table 1: Substantial Equivalence, Trends and other features

Feature	Predicate	Predicate	<u>Primary</u> Predicate	Subject Device	Comments
	<i>NicoletOne K173366</i>	<i>Moberg CNS K080217</i>	<i>Natus NeuroWorks K180421</i>	<i>Natus NeuroWorks</i>	
Numeric & graphical representations					

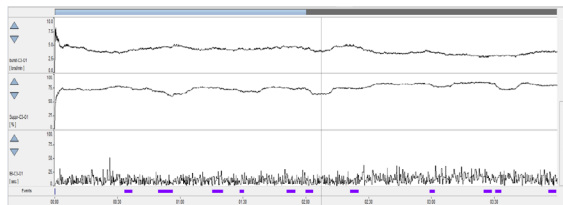
Detailed description of new Trend features:

	NicoletOne K173366 (Predicate device)	Natus NeuroWorks (subject device)	Comments
Description of Burst Suppression trend	<p>The Burst Suppression Trend is an analyzer that has been developed to identify Burst Suppression Pattern in the EEG. It is recognized by a periodic pattern of low voltage (less than 10 μv) and relatively shorter patterns of higher amplitude complexes.</p> <p>Three types of burst channels are available in the Calculated Channels editor:</p> <ul style="list-style-type: none"> - Burst rate: average n° of segments with higher-amplitude and mixed-frequency activity over the analysis window length - % Suppression, “Burst Suppression ratio”, or “BSR”: % of (sum of duration of suppression during analysis window / analysis window length). The default analysis window is 10 min - IBI, “Inter-burst interval”: Duration of the last complete suppression period (will be detected 1 – 2 seconds after arrival of burst ending the suppression...) <p>In addition to the trends, these BS values can be displayed in the Heads-Up toolbar from Natus NeuroWorks.</p>	<p>The Burst Suppression Trend is an analyzer that has been developed to identify Burst Suppression Pattern in the EEG. It is recognized by a periodic pattern of low voltage (less than 10 μv) and relatively shorter patterns of higher amplitude complexes.</p> <p>Three types of burst channels are available in the Calculated Channels editor:</p> <ul style="list-style-type: none"> - Burst rate: average n° of segments with higher-amplitude and mixed-frequency activity over the analysis window length - % Suppression, “Burst Suppression ratio”, or “BSR”: % of (sum of duration of suppression during analysis window / analysis window length). The default analysis window is 10 min - IBI, “Inter-burst interval”: Duration of the last complete suppression period (will be detected 1 – 2 seconds after arrival of burst ending the suppression...) <p>In addition to the trends, these BS values can be displayed in the Heads-Up toolbar from Natus NeuroWorks.</p>	Same

- The Burst Suppression features also eliminate the need to manually count the bursts.

The Burst Suppression Features of NicoletOne also show trend plots and values for **Bursts**, % **Suppression**, and Inter-Burst Interval (**IBI**)

Example of Burst Suppression trends in NicoletOne:

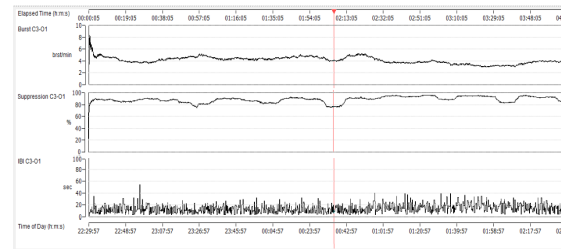


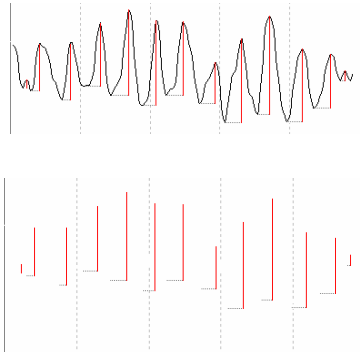
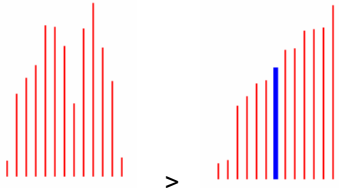
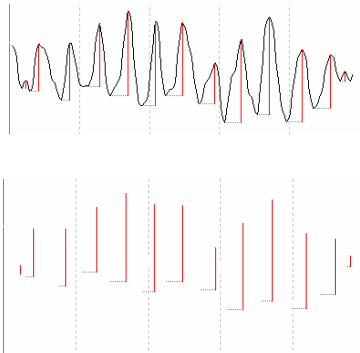
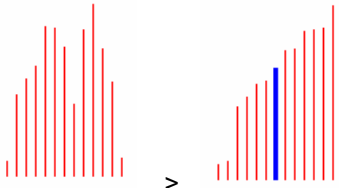
- The Burst Suppression features also eliminate the need to manually count the bursts.

The programming code and the drawing algorithm for Burst Suppression was taken over from NicoletOne software, a product owned by Natus.

The following example show trend plots for Burst Suppression in Natus NeuroWorks on the same study data. Consequently the resulting graphs are identical:

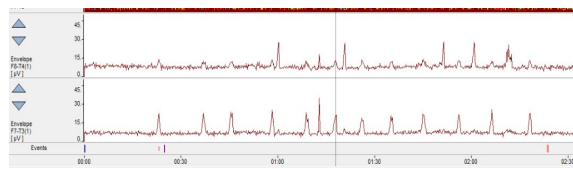
Natus NeuroWorks :



<p>Description of Envelope trend</p>	<p>Envelope trends show a line graph representing variations in amplitude of EEG activity</p> <p>The algorithm is as follows:</p> <ol style="list-style-type: none"> 1. Slice the EEG into blocks of a specific length, ideally 20-30 sec, for better elimination of movement artifacts. 2. For each block, all waves in the EEG are detected, and the peak to peak amplitude is calculated in each wave.  <ol style="list-style-type: none"> 4. The waves are then lined up by size and the median peak to peak amplitude in the block is found. This is the numerical value of the Envelope.  <p>The Envelope trend tracks changes in EEG amplitude but is less sensitive to movement</p>	<p>Envelope trends show a line graph representing variations in amplitude of EEG activity</p> <p>The algorithm is as follows:</p> <ol style="list-style-type: none"> 1. Slice the EEG into blocks of a specific length, ideally 20-30 sec, for better elimination of movement artifacts. 2. For each block, all waves in the EEG are detected, and the peak to peak amplitude is calculated in each wave.  <ol style="list-style-type: none"> 4. The waves are then lined up by size and the median peak to peak amplitude in the block is found. This is the numerical value of the Envelope.  <p>The Envelope trend tracks changes in EEG amplitude but is less sensitive to movement</p>	<p>Same</p>
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artifacts than the total power trend. T

Example of an envelope trend in NicoletOne:

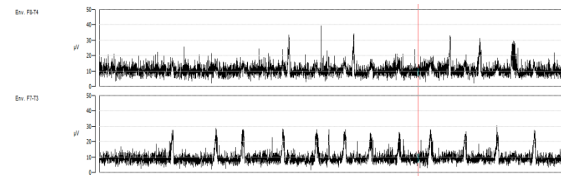


artifacts than the total power trend.

The programming code and the drawing algorithm for Envelope was taken over from

NicoletOne software, a product owned by Natus.

The following examples show trend plots for Envelope trend in Natus NeuroWorks on the same study data as the example for Nicoletone. Consequently the resulting graphs are identical:

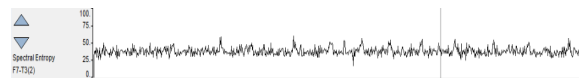


Description of Spectral Entropy (SEN) trend

Spectral Entropy shows a line graph representing the “complexity” or “regularity” of a signal.

SEN can take values from 0 (if the signal is completely regular, e.g. a sine wave) to 100 (if the spectrum is that of uncorrelated white noise).

Example of a spectral Entropy trend in Nicoletone:



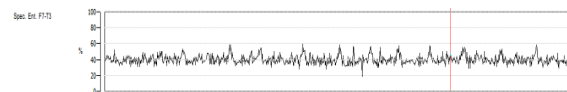
Spectral Entropy shows a line graph representing the “complexity” or “regularity” of a signal.

SEN can take values from 0 (if the signal is completely regular, e.g. a sine wave) to 100 (if the spectrum is that of uncorrelated white noise).

The programming code and the drawing algorithm for Spectral Entropy was taken over from NicoletOne software, a product owned by

Natus.

The following example show the trend plot for Spectral Entropy in Natus NeuroWorks on the same study data as the example for Nicoletone. Consequently the resulting graphs are identical:

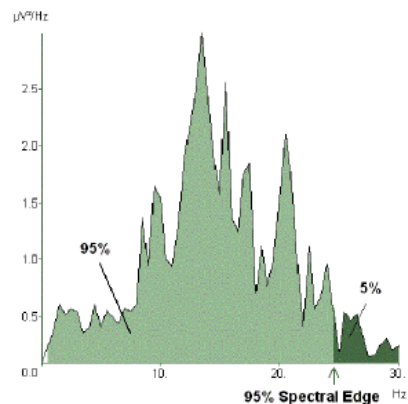


Same

Description of Spectral Edge trend

The 95% Spectral Edge is the frequency below which one finds 95% of the total power.

The spectral edge and median frequencies are derived from the power spectrum from a block of EEG:

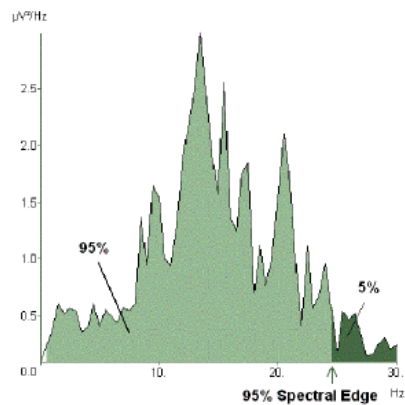


In the same way it is possible to define 90%, 85% etc. spectral edge frequency.

Example of a spectral Edge trend in Nicoletone:

The 95% Spectral Edge is the frequency below which one finds 95% of the total power.

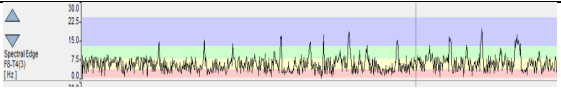
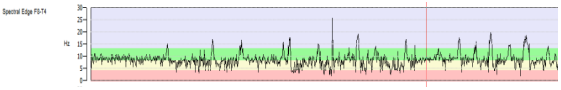
The spectral edge and median frequencies are derived from the power spectrum from a block of EEG:



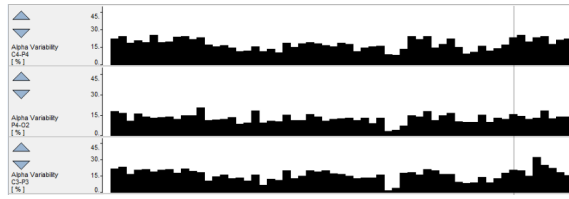
In the same way it is possible to define 90%, 85% etc. spectral edge frequency.

The algorithm for Spectral Edge was taken over from NicoletOne software, a product owned by Natus.

Same

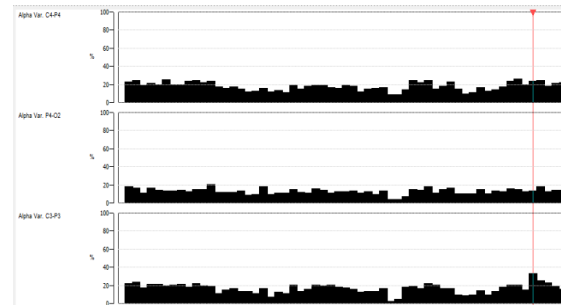
		<p>The following example show the trend plot for Spectral Edge trend in Natus NeuroWorks on the same study data as the example for Nicoletone. Consequently the resulting graphs are identical:</p> 	
<p>Description of Alpha Variability</p>	<p>Alpha variability is the analysis of the change in power in the 6Hz to 14Hz band (including alpha) compared to the wide band power between 1Hz and 20Hz.</p> <p>The Alpha Variability Trend/Relative Alpha, takes a moving average of the spectrum. The moving average contains 60 blocks of data where one block is typically 2 seconds.</p> $\text{Alpha variability} = \frac{\text{BandPower}(6\text{Hz}, 14\text{Hz})}{\text{BandPower}(1\text{Hz}, 20\text{Hz})}$	<p>Alpha variability is the analysis of the change in power in the 6Hz to 14Hz band (including alpha) compared to the wide band power between 1Hz and 20Hz.</p> <p>The Alpha Variability Trend/Relative Alpha, takes a moving average of the spectrum. The moving average contains 60 blocks of data where one block is typically 2 seconds.</p> $\text{Alpha variability} = \frac{\text{BandPower}(6\text{Hz}, 14\text{Hz})}{\text{BandPower}(1\text{Hz}, 20\text{Hz})}$	<p>Same</p>

Example of a Alpha Variability trend in NicoletOne:



The algorithm for Alpha Variability was taken over from NicoletOne software, a product owned by Natus.

The following examples show trend plots for Alpha Variability trend in NicoletOne and in Natus NeuroWorks on the same study data as the example for NicoletOne. Consequently the resulting graphs are identical:



These predicate devices support features and technology equivalence of the Natus NeuroWorks software under review. As indicated, the Natus NeuroWorks software and the predicate devices are equivalent in features and technical characteristics.

The Natus NeuroWorks software and predicate devices are not life supporting or life sustaining devices. The Natus NeuroWorks software is intended for use only by qualified and trained medical practitioners in clinical and research environments, who evaluate the software output with their clinical experience and judgment to provide diagnostic conclusions about the patient's condition.

Similarly to the predicate devices, Natus NeuroWorks software provides the qualified users with computer assisted scoring of events which will mark sections of the recorded signals for subsequent review by the user. These functions are provided as computer-aided tools. Users are instructed to review, accept or reject the results of the assisted scoring tools in accordance with their professional judgment.

Natus NeuroWorks software and all predicates include features for acquisition of synchronized video recording/review, audio/visual threshold based alerts for calibrated external devices (pulse oximeter) as well as trending of any collected data for summary review and reporting.

The differences between Natus NeuroWorks and the predicate devices are mainly related to user workflow. There are no major differences that significantly alter the intended use or raise new issues of safety or effectiveness. The predicates devices NeuroWorks software (K180421) and NicoletOne (K173366), as well as the device under review, Natus NeuroWorks software, have equivalent intended use: to record and process EEG/PSG and other physiological signals to assist in the diagnosis of various neurological disorders, sleep disorders and sleep related respiratory disorders affecting patients in all age groups.

Brief Summary of Performance Tests:

<i>BioCompatibility</i>	Natus NeuroWorks is a software-only device. Biocompatibility testing is not applicable.
Electrical Safety and EMC	Natus NeuroWorks is a software-only device. Electrical safety evaluation and EMC evaluation is not applicable.
Animal Study	There were no animal studies performed for this submission.
Clinical Study	There were no clinical studies performed for this submission.

Software

The Natus NeuroWorks software was designed and developed according to a robust software development process, and was rigorously verified and validated. Software information is provided in accordance with internal requirements and the following FDA guidance documents and standards:

- *The content of premarket submissions for software contained in medical devices, 11 May 05.*
- *Off-the-shelf software use in medical devices, 09 Sep 99.*
- *General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02.*
- *Content of premarket submissions for management of cybersecurity in medical devices, 02 Oct 14.*
- *Cybersecurity for networked medical devices containing off-the-shelf (OTS) software, 14 Jan 05*
- *IEC 62304: 2006, Medical device software – Software life cycle processes*

Results indicate that the Natus NeuroWorks software complies with its predetermined specifications, the applicable guidance documents, and the applicable standards.

*Performance
Testing – Bench*

The Natus NeuroWorks software was verified for performance in accordance with internal requirements and the applicable clauses of the following standards:

- IEC 62304: 2006, Medical device software – Software life cycle processes
- *IEC 62366: 2007, Am1: 2014, Medical devices – Application of usability engineering to medical devices*
- *IEC 60601-1-6 Medical electrical equipment-part 1-6 General requirements for basic safety and essential performance –Collateral standard :Usability*
- ISO 14971: 2012, Medical devices – Application of risk management to medical devices

Results indicate that the Natus NeuroWorks software complies with its predetermined specifications and the applicable standards.

In addition , Bench and performance testing was performed to confirm

- Functional testing of the supported Amplifiers with NeuroWorks software
- Functional testing of the supported Neuroworks Workflows within the software
- Functional testing of the supported Peripheral Components within the software
- Interoperability between the NeuroWorks amplifiers and Physiological Monitoring units.
- Functional and bench testing of the Trend data with Neuroworks software.
- Comparison testing of the Trend data between Neuroworks and Predicate device (NicoletOne software)

Results indicate that the Natus NeuroWorks software complies with its predetermined specifications and the applicable standards.

Conclusion

The substantial equivalence of the Natus Neuroworks software with the predicate devices was demonstrated by testing in compliance with the Design Control process. The intended use and technology of the Natus Neuroworks software is similar to that of the predicate device(s). Verification and Validation were performed to ensure no new questions of safety or effectiveness are raised. The results of these activities demonstrate that the Natus Neuroworks software is as safe, as effective, and performs as well as or better than the predicate devices.