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July 20, 2018

Natus Neurology Incorporated
Martin Dockter
Sr. Regulatory Affairs Manager
3150 Pleasant View Road
Middleton, Wisconsin 53562

Re: K173366
Trade/Device Name: NicoletOne
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLZ, OMB, OMA, OLT, ORT
Dated: June 15, 2018
Received: June 18, 2018

Dear Martin Dockter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Valerie A. Flournoy -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173366

Device Name
NicoletOne

Indications for Use *(Describe)*
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.

NicoletOne software allows:
• 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 as well as data ranges for trended values.

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.

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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K173366 - 510(k) SUMMARY

Submitted by: Natus Neurology Incorporated
3150 Pleasant View Road
Middleton, WI 53562

Contact Person: Martin A. Dockter, *Sr. Regulatory Affairs Specialist*
Tel.: (858) 260-2552
Fax: (858) 455-8298
E-mail: martin.dockter@natus.com

Date Prepared: July 17, 2018

Proprietary Name: NicoletOne

Common Name: Electroencephalograph

Classification Name: Automatic event detection software for full-montage electroencephalograph

Product code: OLZ (primary), OMB, OMA, OLT, ORT

Device Class: II

Regulation Number: 21 CFR 882.1400

Predicate Device: Twin Plus (K012976) primary; Moberg CNS (K080217); Natus SleepWorks (K090277)

Description:

1. **Overview NicoletOne Software**
   The NicoletOne application is a software product for digital electroencephalography, long term monitoring in Epilepsy, intensive care unit (ICU) monitoring, and polysomnography that runs on a panel PC, desktop or laptop computer. It is a Windows based application used by trained medical professionals to investigate brain function and sleep disorders.
2. **Main Functional Areas**
   The NicoletOne application collects and displays continuous physiological waveform data (via a Natus digital amplifier), and digital audio/video (via standard audio/video equipment). After collecting and saving the signals, it provides tools and analyzers to analyze the signals, which aid in the interpretation of an EEG or PSG study. The software consists of four main functional areas:
   - **Data Acquisition & Display** - Real time collection of EEG, PSG and other physiological parameters. The data is stored and displayed in real time by the NicoletOne software on the acquisition computer and made available for subsequent review by a trained medical professional.

   - **Scoring/Review & Analysis** - The NicoletOne software application has features that facilitate study navigation, event marking, scoring, review of synchronized digital video, and data trends required by medical professionals in order to properly analyze and interpret the study data. In addition to allowing users to manually mark events for both electroencephalography (EEG) and

polysomnography (PSG) studies the NicoletOne software also provides optional computer assisted event marking analyzers for certain events.

- **Report Generation** - Once the digital electroencephalography (EEG) or polysomnography (PSG) data has been acquired scored and reviewed by medical professionals the NicoletOne and NicVue software is used to generate a report of the study. The generated reports are associated with the patient in the patient database. NicoletOne also includes the ability to customize report templates to conform to individual facilities standards and policies.

- **Archiving & Data Management** - Once the digital electroencephalography (EEG) or polysomnography (PSG) data has been acquired scored and reviewed by medical professionals the NicoletOne and NicVue software is used to generate a report of the study. The generated reports are associated with the patient in the patient database. NicoletOne also includes the ability to customize report templates to conform to individual facilities standards and policies.

3. Typical work flow using the NicoletOne Application software

During the Acquisition phase, the software collects data based on user selected sampling rates, amplifier set-up, and amplifier calibrations. These three factors define how the software collects and displays the data in real-time. The recording is saved on the hard disk of the user's computer in a raw data format. The user can customize displays, observations, event markers, and tags.

4. Computer-assisted scoring analyzers and trending

The NicoletOne software contains eleven (11) computer-assisted analyzers and supports twenty (20) trends. All automatic detection tools are provided as time saving aids to assist trained medical practitioners in the review and analysis of vast amounts of data. Each computer-assisted analyzer runs a specific type of event marking or numeric value processing in the study and each can be enabled individually as needed at the discretion of the user. The parameters used in the computer-assisted analyzers depend on available input signals in the study as well as user defined settings. All output from computer assisted analyzers require medical professional review and acceptance.

The eleven computer-assisted scoring analyzers are:

- Spike Detection
- Seizure Detection
- Apnea/Hypopnea Detection
- Limb Movement Detection
- Desaturation Detection
- Oxygen Saturation
- Heart Rate Detection
- Body Position Detection
- CPAP
- Automatic Detection
- Threshold Detection

5. Diagnosis

The NicoletOne software does not make any decisions that result in any automatic diagnosis or treatment. All software output is subject to review by the medical professional, and can be modified, overridden or deleted. The software allows the qualified user to review all raw data collected and perform data analysis as required. NicoletOne does not provide any final diagnostic conclusion about the patient's condition. Neither the computer nor the software controls the delivery of energy, the administration of drugs, or another form of life sustaining function to the patient.

The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments. Users of the NicoletOne software are solely responsible for all data collected, and are expected to assess and analyze this data to ensure its accuracy and completeness.

Indications for Use:

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.

NicoletOne software allows:

- 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 as well as data ranges for trended values.

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.

Comparison to Predicate Devices:

The NicoletOne software application is being compared to the software applications in the predicates Twin Plus (K012976), Moberg CNS (K080217) as well as the Natus SleepWorks software (K090277). These four software applications acquire, display, store, and archive electroencephalographic signals from the brain and other signals (such as electromyography, respiratory and/or oximetry signals) 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 NicoletOne software application under review to the three predicate devices.

Table 1: Substantial Equivalence, aEEG, Trends and other features

Feature	Predicate ***Twin Plus K012976***	Predicate ***Moberg CNS K080217***	**Primary** Predicate ***SleepWorks K090277***	Subject Device ***NicoletOne***	Comments
Device Class	Class II	Class II	Class II	Class II	Identical
Class Name	Electroencephalograph (EEG)	EEG	EEG	EEG	Identical
Product Code	GWQ	OMA (primary); GWQ, MHX, MUD, OLT, ORT	OLZ	OLZ (primary); OMB, OMA, OLT, ORT	Includes EEG/PSG software product codes from all predicates plus OMB for assisted scoring EEG algorithms.

Table 1: Substantial Equivalence, aEEG, Trends and other features

Feature	Predicate ***Twin Plus K012976***	Predicate ***Moberg CNS K080217***	**Primary** Predicate ***SleepWorks K090277***	Subject Device ***NicoletOne***	Comments
Classifying Regulation (Primary)	882.1400	882.1400	882.1400	882.1400	Identical
Intended User	Medical Professional	Medical Professional	Medical Professional	Medical Professional	Identical
Indications for Use	This software is intended for use by qualified research and clinical professionals with specialized training in the use of EEG and PSG recording instrumentation for the digital recording, playback, and analysis of physiological signals. It is suitable for digital acquisition, display, comparison, analysis, and archiving of EEG potentials and other rapidly changing physiological parameters.	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. 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	The Sleepworks software works in conjunction with Connex, Trex or Netlink amplifiers intended for polysomnography studies. The software allows recording, displaying, analysis, printing and storage of physiological signals to assist in the diagnosis of various sleep disorders and sleep related respiratory disorders. The Sleepworks allows: 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	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. NicoletOne software allows: 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	Included EEG intended use wording from Moberg CNS. Removed reference to ICP from Moberg CNS. Included PSG wording from SleepWorks and removed references to proprietary amplifiers. The Twin Plus supports automatic Spike and Seizure event detection.

Table 1: Substantial Equivalence, aEEG, Trends and other features

Feature	Predicate *Twin Plus* *K012976*	Predicate *Moberg CNS* *K080217*	Primary Predicate *SleepWorks* *K090277*	Subject Device *NicoletOne*	Comments
		clinical research settings.	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 as well as data ranges for trended values; Sleep Works software 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.	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 as well as data ranges for trended values. 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.	
User input	Mouse/Keyboard	Mouse/keyboard	Mouse/keyboard	Mouse/keyboard	Same
Acquire, display, store, and archive EEG/PSG Data	Yes	Yes	Yes	Yes	Same
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	No	Yes SaO2, heart rate	Equivalent
Power	Not Applicable	NA	NA	NA	Software operating on a computer.
EEG Software Detectors					

Table 1: Substantial Equivalence, aEEG, Trends and other features

Feature	Predicate ***Twin Plus K012976***	Predicate ***Moberg CNS K080217***	**Primary Predicate** ***SleepWorks K090277***	**Subject Device** ***NicoletOne***	**Comments**
Spike Detection	Yes (Manual & Computer Assisted)	Yes (Manual)	No	Yes (Manual & Computer Assisted)	The Twin Plus supports automatic spike and seizure event detection. The Twin Plus 510(k) declares the automatic spike detection and seizure detection feature is a direct copy of the spike detection and seizure detection feature in the Telefactor SzAC K870450.
Seizure Detection	Yes (Manual & Computer Assisted)	Yes (Manual)	No	Yes (Manual & Computer Assisted)	
Burst Suppression	No	Yes	No	Yes	Equivalent
Amplitude Integrated EEG (aEEG)	No	Yes	No	Yes	Equivalent
Power Spectrum	No	Yes	No	Yes	Equivalent
Envelope Trend	No	Yes	No	Yes	Equivalent
Total Power Trend	No	Yes	No	Yes	Equivalent
Band Power Trend	No	Yes	No	Yes	Equivalent
Spectrogram	No	Yes	No	Yes	Equivalent
Spectral edge/Median freq. Trends	No	Yes	No	Yes	Equivalent
Peak Frequency Trend	No	Yes	No	Yes	Equivalent
Spectral Entropy trend	No	Yes	No	Yes	Equivalent
Frequency Ratio Trend	No	No	No	Yes	Equivalent
Alpha Variation Trend	No	No	No	Yes	Equivalent
PSG Software Detectors					
Respiratory event marking	Yes (Manual & Computer Assisted)	Yes (Manual)	Yes (Manual & Computer Assisted)	Yes (Manual & Computer Assisted)	Equivalent

Table 1: Substantial Equivalence, aEEG, Trends and other features

Feature	Predicate *Twin Plus K012976*	Predicate *Moberg CNS K080217*	Primary Predicate *SleepWorks K090277*	Subject Device *NicoletOne*	Comments
Sleep staging/ scoring	Yes (Manual & Computer Assisted)	Yes (Manual)	Yes (Manual & Computer Assisted)	Yes (Manual)	Equivalent
Arousal Event Marking	Yes (Manual & Computer Assisted)	Yes (Manual)	Yes (Manual & Computer Assisted)	Yes (Manual)	Equivalent
Limb movements event marking	Yes (Manual)	Yes (Manual)	Yes (Manual & Computer Assisted)	Yes (Manual & Computer Assisted)	Equivalent
Snore event marking	Yes (Manual)	Yes (Manual)	Yes (Manual & Computer Assisted)	Yes (Manual)	Equivalent
Oxygen Desaturation event marking	Yes (Manual)	Yes (Manual)	Yes (Manual & Computer Assisted)	Yes (Manual & Computer Assisted)	Equivalent
Heart Rate data trend & summary	Yes	Yes	Yes	Yes	Same
Other features					
Synchronized patient video	Yes	Yes	Yes	Yes	Same
Oximetry data display and reporting	Yes	Yes	Yes	Yes	Same
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	No	Yes	Yes	Yes	Same
Signals recorded (output)	Respiratory Effort (abdomen and chest) Airflow Pressure Snore Body Position Pulse Rate Oximeter ECG EEG EMG DC Leg Movement and other signals	Respiratory Effort (abdomen and chest) Airflow Pressure Snore Body Position Pulse Rate Oximeter ECG EEG EMG EOG DC Leg Movement and other signals	Respiratory Effort (abdomen and chest) Airflow Pressure Snore Body Position Pulse Rate Oximeter ECG EEG EMG EOG DC Leg Movement and other signals	Respiratory Effort (abdomen and chest) Airflow Pressure Snore Body Position Pulse Rate Oximeter ECG EEG EMG EOG DC Leg Movement and other signals	Equivalent

Table 1: Substantial Equivalence, aEEG, Trends and other features

Feature	Predicate ***Twin Plus K012976***	Predicate ***Moberg CNS K080217***	**Primary Predicate** ***SleepWorks K090277***	Subject Device ***NicoletOne***	Comments
	required for sleep studies	required for sleep studies	required for sleep studies	required for sleep studies	
Report generation including counts indexes, max / min/ average/ duration, range based data summaries. Numeric & graphical representations	Yes, customizable templates	Yes, customizable templates	Yes, customizable templates	Yes, customizable templates	Same

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

The NicoletOne software and predicate devices are not life supporting or life sustaining devices. The NicoletOne 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, NicoletOne 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.

NicoletOne software and all three 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.

NicoletOne and the predicate SleepWorks (K090277) include computer assisted event marking algorithms for respiratory and limb movements. The NicoletOne algorithm performance is similar to the previously cleared algorithms within the SleepWorks (K090277) application.

The differences between NicoletOne 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 Twin Plus (K012976) and SleepWorks (K090277), as well as the device under review, NicoletOne 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.

The NicoletOne software and predicate devices are not life supporting or life sustaining devices. The NicoletOne 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.

Brief Summary of Performance Tests:

Biocompatibility
NicoletOne is a software-only device. Biocompatibility testing is not applicable.

Electrical Safety and EMC
NicoletOne is a software-only device. Electrical safety evaluation and EMC evaluation is not applicable.

Software Verification
Bench verification and validation testing of the NicoletOne application was performed in compliance with the Natus Medical incorporated design control process. Testing results demonstrate that the NicoletOne software meets the design specification and performs as specified.

Animal Study
There were no animal studies performed for this submission.

Clinical Study Summary – Respiratory and Limb Movement Assisted-scoring Analyzers

1.1. Participants
Forty-nine PSG sleep studies were collected. All patients involved in this study were adult patients (32-85 years old) with a clinical indication for a sleep study. The patient data were de-identified and applied as subject data to this study.

1.2. Dataset description
Total Number of Subjects: 49 per event evaluated
Total Number of scored Epochs (30 Sec): ≥ 43,480
Total Number of Hours: 361:31:00
Average number of epochs per subject: 887.3
Minimum number of epochs per subject: 799
Maximum Number of epochs per subject: 983

Data from 49 subjects were evaluated for respiratory and limb movement events. All epochs from these subjects were scored.

1.3. Objective of the study
The goal of this clinical validation study was to establish that the performance of the NicoletOne assisted scoring software for respiratory and limb movement events compared to the Majority are equivalent with the predicate device and acceptable for clinical use. For the purpose of this study the Majority is defined as:
For respiratory events, a Majority rule of at least 2 out of 3 manual expert scorers agree on the type(s) of event(s) in an epoch or the lack of the event in the epoch.
For limb movement, a majority rule of at least 2 out of 3 manual expert scorers agree on the presence of the event type in the epoch.

1.4. PSG acquisition protocol

For this study, the following signals were recorded from each subject:

- Six (6) Electroencephalogram ([EEG] channels: F3, F4, C3, C4, O1, and O2.
- Two (2) Electrooculogram (EOG) channels
- Submental and bilateral tibial electromyogram (EMG)
- Electrocardiogram (ECG)
- Airflow (nasal-oral thermistor and nasal pressure sensors or PAP flow)
- Chest and abdominal movement using respiratory inductance Plethysmography.
- Pulse oximetry (SpO2) and pulse rate

1.5. PSG analysis protocol

All physiologic data were collected and stored on a NicoletOne System. The ECG, EEG, EMG, EOG, Snoring channels, Airflow, Chest and abdominal movement channels were collected along with Pulse oximetry channels.

The raw PSG recordings were de-identified, randomized and provided to three experienced and certified PSG specialists, including one board certified sleep specialist, who independently marked events of interest in each epoch, applying the following criteria.

1.5.1 Respiratory event expert scoring requirements

All study epochs will be scored for one or more of the following types of respiratory events in each 30 second epoch. Respiratory event scoring is defined in the following table.

Respiratory Event	Definition
Obstructive Apnea	Apply AASM VIII. Respiratory Rules; Part 1: Rules for Adults, Section "C. Scoring of Apneas".
Central Apnea	Apply AASM VIII. Respiratory Rules; Part 1: Rules for Adults, Section "C. Scoring of Apneas".
Mixed Apnea	Apply AASM VIII. Respiratory Rules; Part 1: Rules for Adults, Section "C. Scoring of Apneas".
Hypopnea	Apply AASM VIII. Respiratory Rules; Part 1: Rules for Adults, Section "D. Scoring of

1.5.2 Leg movement scoring requirements

Score leg movements per the AASM Section VII Movement Rules.

1.5.3 Analyzers

Separate from the expert review, all PSG studies were also analyzed by NicoletOne assisted-scoring analyzers at default values for:

- Central apnea
- Mixed apnea
- Obstructive apnea
- Hypopnea
- Limb movement

1.6. Outcomes

Positive Percent Agreement (PPA) between NicoletOne assisted-scoring analyzers compared to the Reference standard were measured on an epoch basis. The mean and 95% confidence interval (CI) of the PPA and false detection rate per hour for event detection assisted-scoring modules are shown in the following table.

PPA and False Detection Rate Per Hour of NicoletOne Event Detection Assisted Scoring modules

	NicoletOne			
	PPA		FD/h	
Event	Mean	95% CI	Mean	95% CI
Central Apnea	99.1%	98.8% to 99.5%	0.6	0.37 to 1.07
Mixed Apnea	99.6%	99.3% to 99.8%	0.3	0.15 to 0.66
Obstructive Apnea	98.6%	97.5% to 99.3%	0.2	0.11 to 0.48
Hypopnea	86.8%	84.1% to 89%	9.0	7.41 to 10.89
Limb Movement	93.3%	90.9% to 95.3%	3.7	2.01 to 4.64

1.7. Clinical Study Conclusion

Compared to the Reference standard, NicoletOne assisted-scoring modules showed performance levels comparable to the manual markings of expert reviewers. The device performance is clinically equivalent to the Reference standard (majority rule) as constructed for this study, similar to results reported in the literature and to performance reported for other commercially available devices.

510(k) Summary Conclusions:

The substantial equivalence of the NicoletOne with the predicate Natus SleepWorks product was demonstrated by software verification testing and clinical validation. The non-clinical data support the safety of the device. The software verification and validation demonstrate that the NicoletOne device should perform as intended in the specified use conditions. The clinical validation of the Respiratory and Limb Movement Assisted-scoring Analyzers demonstrates that the NicoletOne device performs similarly to the predicate device that is currently marketed for the same intended use.