510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

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DEVICE:

TRADE NAME: Positional Sleep Assessment System (PoSAS) Software

COMMON/USUAL NAME: PoSAS, PoSAS Software

CLASSIFICATION NAMES: 868.2375 Breathing frequency monitor

REVIEW PANEL: Anesthesiology

PRODUCT CODE: MNR

PREDICATE DEVICE(S):

Apnea Risk Evaluation System (ARES) K112514

REFERENCE DEVICE(S):

Night Shift Software K140190

Sleep Profiler K153412

nVISION Data Management software K033307

DEVICE DESCRIPTION:

The Positional Sleep Assessment System (PoSAS) Software is a standalone desktop software application that provides the capability to generate reports from the data acquired with the Advanced Brain Monitoring (ABM) Night Shift (K140190) and/or a pulse oximeter. The PoSAS Software is currently compatible with the Nonin WristOx$_2$ (model 3150) cleared in K102350.

The Night Shift is a small neck-worn device with software indicated for use in reporting position, movement, and sound so that positional changes in sleep quality and snoring can be assessed for adult patients only. The Nonin WrisOx$_2$ is a small wrist-worn device indicated for use in measuring, displaying, and storing functional oxygen saturation of arterial hemoglobin (SpO$_2$) and pulse rate of adults and pediatric patients. The PoSAS Software is intended to be used in healthcare facilities (e.g. Clinician's office) to transfer and analyze data obtained with the Night Shift and WristOx$_2$ by adult patient's in the home or sleep lab. The Night Shift uses a USB 2.0 data cable to transfer data via Standard USB 2.0 flash drive and the WristOx$_2$ uses a proprietary USB 2.0 data cable to transfer data via USB 2.0 Virtual COM Port.

Once the devices are recognized, the PoSAS Software graphical user interface (GUI) enables the user to synchronize the devices by writing the same computer date/time (down to the second) to each of the devices. The PoSAS Software also allows for the data to be erased from both the Night Shift and WristOx$_2$ devices, and allows for the Night Shift device settings (I.e. Vibration feedback on, Vibration feedback off, or Trial mode) to be updated prior to recording.

Once the clock times from the two devices are synchronized, and the user has set the desired settings of the Night Shift device (i.e., identical to features available using Night Shift software), the Night Shift and WristOx$_2$ are worn by a patient to record sleep study data. The PoSAS Software reads the study files and recognizes the respective clock times within each file, and aligns the data for generation of a PoSAS report.

The PoSAS Software report presents the Night Shift data, analyzed pulse oximeter data, and combines the positional data from the Night Shift with the analyzed results from the pulse oximetry data.

A PoSAS Software report can be generated either from the data saved on the connected Night Shift and pulse oximeter devices or from data saved to the hard disk of the personal computer. Data from the Night Shift is displayed on the PoSAS Software report without modification. The

PoSAS Software calculates oximetry data based on the once per second SpO_2 and pulse data acquired by the pulse oximeter. 3% or 4% desaturations and pulse events (6 bpm change) are also calculated. The PoSAS software combines Night Shift position information with calculated oximetry data to present metrics based on the patient's position (supine or non-supine). A clinician's assessment of his/her patient's "Sleep Quality" is enabled by the PoSAS Report's inclusion of the following study metrics:

- Recording Time
- Sleep Time
- % Efficiency
- Wake After Sleep Onset (WASO)
- Awakenings
- Supine Time
- % Supine Time
- Overall Snoring > 50dB
- Supine Snoring > 50dB
- Non-supine Snoring > 50dB
- No. Supine Attempts
- Typical Feedbacks
- Minimum Feedbacks
- Maximum Feedbacks
- Graphical presentation of:
    - Sleep/wake
    - Position
    - Snoring
    - Mean SpO_2
    - Minutes SpO_2 < 90%
    - Minutes SpO_2 < 88%
- Lowest Desaturation
- Mean Pulse Rate (BPM)
- Std Dev Pulse Rate
- Min Pulse
- Max Pulse
- SpO_2 3% and 4% desaturation events
- SpO_2 3% and 4% desaturation index
- Pulse events (6 bpm change) and events/hr
- Pulse Events/hr Overall
- Supine SpO_2 3% and 4% desaturation index
- Non-supine SpO_2 3% and 4% desaturation index
- Pulse Events/hr Supine
- Pulse Events/hr Non-supine
- SpO_2 Overall/Non-Supine
- Graphical Presentation of:
    - Pulse
    - SpO_2
    - 3% and 4% desaturation events
    - Pulse events (6 bpm change)

The PoSAS Software is a software-only desktop PC application that is validated to be compatible with Microsoft Windows 7, 8, and 10 operating systems and 64-bit processors.

INDICATIONS FOR USE:

The Positional Sleep Assessment System (PoSAS) Software is a software-only device intended for use by healthcare professionals to access previously recorded data for review and interpretation of sleep length, sleep disruptions, snoring, and positional sleep disordered breathing events in adults. The PoSAS Software is used in healthcare facilities to generate sleep study reports from data obtained with the Night Shift and pulse oximeter devices; reports include sleep/wake, position, snoring, SpO_2, pulse rate, pulse event (6 bpm change), and/or

desaturation event information. The report requires clinician interpretation of the results; it does not suggest a course of treatment or generate a diagnosis.

SUBSTANTIAL EQUIVALENCE DISCUSSION:

Both the PoSAS Software and the predicate ARES device have the same intended use of analyzing physiological signals acquired during sleep and generating and presenting reports. Both the PoSAS Software and the ARES provide sleep quality (i.e. sleep length, sleep disruptions, and snoring) and positional sleep disordered breathing event information.

The PoSAS Software has the same intended use and uses the similar fundamental technology as the predicate device ARES. The following table compares indications and specifications of the PoSAS Software to the ARES.

TABLE 5.1: COMPARISON TO PREDICATE DEVICE

Specification	**Proposed Device: PoSAS Software (K172799)**	**Predicate Device: ARES (K112514)**	**Discussion Differences**
Trade Name	Positional Sleep Assessment System (PoSAS) Software	Apnea Risk Evaluation System (ARES)	
Model	Desktop	Desktop and Portal	Equivalent. The PoSAS Software is only available as a desktop application.
Classification	MNR, Ventilatory Effort Recorder	MNR, Ventilatory Effort Recorder	Identical.

Specification	Proposed Device: PoSAS Software (K172799)	Predicate Device: ARES (K112514)	Discussion Differences
Indications for Use	The Positional Sleep Assessment System (PoSAS) Software is a software-only device intended for use by healthcare professionals to access previously recorded data for review and interpretation of sleep length, sleep disruptions, snoring, and positional sleep disordered breathing events in adults. The PoSAS Software is used in healthcare facilities to generate sleep study reports from data obtained with the Night Shift and pulse oximeter devices; reports include sleep/wake, position, snoring, SpO_2, pulse rate, pulse event (6 bpm change), and/or desaturation event information. The report requires clinician interpretation of the results; it does not suggest a course of treatment or generate a diagnosis.	The Apnea Risk Evaluation System (ARES) is indicated for use in the diagnostic evaluation by a physician of adult patients with possible sleep apnea. The ARES can record and score respiratory events during sleep (e.g., apneas, hypopneas, mixed apneas and flow limiting events). The device is designed for prescription use in home diagnosis of adults with possible sleep-related breathing disorders.	Equivalent. The ARES includes both a hardware recorder and analysis software. The PoSAS Software is intended to generate sleep reports from data for adult patients like the ARES Software. The PoSAS Software uses a subset of the signals as compared to the ARES so it is not intended for diagnosis and cannot present as many respiratory events. Because the accessory Night Shift input device is indicated for use in positional sleep disordered breathing, the PoSAS Software evaluates positional sleep disordered breathing, whereas the ARES can be used for positional and non-positional sleep disordered breathing.
Intended Use	Analyze physiological data acquired during sleep and present a report.	Analyze physiological data acquired during sleep and present a report. Acquire physiological data during sleep.	Equivalent. The PoSAS Software and ARES Software both analyze physiological data acquired during sleep and present result reports. The ARES additionally acquires sleep data.
Patient Population	Adults	Adults	Identical
Environment of Use	Healthcare Facility (data analysis and reporting)	Home (data acquisition) Physician office (data analysis and reporting)	Equivalent. PoSAS Software may be used in clinician offices for data analysis and reporting.

Specification	Proposed Device: PoSAS Software (K172799)	Predicate Device: ARES (K112514)	Discussion Differences
Technology			
Principle of Operation	Displays and/or performs analysis and displays previously acquired physiological signals, and delivers reports for the clinician, depending on the selected signal inputs and/or the number of nights the data were acquired.	Acquires and performs analysis of previously acquired physiological signals, presents the signals for editing, and delivers reports for the clinician, depending on the selected signal inputs and/or the number of nights the data were acquired.	Different. The PoSAS Software's principle of operation is similar to the ARES in that it analyzes previously acquired signals and delivers reports for the clinician. Unlike the ARES, the PoSAS displays some data without analysis (i.e. all data provided by the Night Shift), it analyzes fewer signals (i.e. only Pulse rate and SpO_2), and it does not present any of the ARES signals that can be manually edited.
Compatible Devices	Advanced Brain Monitoring's Night Shift Recorder/Therapy Device (K140190) Nonin $WristOx_2$ Wireless Pulse Oximeter (K102350)	ARES Unicorder (K112514)	Equivalent. Both PoSAS and ARES Software analyze data collected by sleep recording devices. The ARES recorder and software were cleared under the same 510(k) K112514.
Software	Software provides device management, data analysis, and report presentation on desktop software.	Software provides device management, data analysis, visual signal inspection, and report presentation on desktop and web-portal software.	Different. Both the PoSAS Software and ARES provide device management, analyze data, and generate reports with desktop software. PoSAS Software is not available as a web-based application and the signals cannot be visually inspected.
Materials	N/A – software only	Case: ABS Blend Enclosure Strap: non-latex elastic, polypropylene shield, Velcro velstretch brand tape Cannula: Salter Labs SO-1314	The PoSAS Software and ARES Software both analyze data that has been previously recorded. The ARES includes the data acquisition Unicorder unit.

Specification	Proposed Device: PoSAS Software (K172799)	Predicate Device: ARES (K112514)	Discussion Differences
Signals Processed and Analyzed	• SpO_2 • Pulse Rate	• SpO_2 • Pulse Rate • Head movement and position • Snoring sounds • Airflow • EEG • Respiratory effort	Different. The PoSAS Software analyzes a subset of signals of ARES. Analysis of SpO_2 and pulse rate is equivalent to the ARES, as the PoSAS is based on the similar algorithms as the ARES, and is identical to the algorithms used for the Sleep Profiler (reference device). PoSAS Software combines positional data obtained from the accessory Night Shift device with the analyzed SpO_2 and Pulse data to determine positional-related and SpO_2/Pulse statistics.
Data Displayed on Report	**Displayed from Night Shift study.acq file:** • Recording Time • Sleep Time • % Sleep Efficiency • Wake After Sleep Onset (WASO) • Awakenings • Supine Time • % Supine Time • Overall Snoring > 50dB • Supine Snoring > 50dB • Non-supine Snoring > 50dB • No. Supine Attempts • Typical Feedbacks • Minimum Feedbacks • Maximum Feedbacks **Graphical presentation of:** • Sleep/wake • Position • Snoring	**Calculated and reported:** • Recording time • Sleep Time • % Sleep Efficiency • Measures of sleep/wake • Supine Time • % Supine Time • % time by sleep stage • % Time Snoring > 30dB, 40dB, and 50dB • Overall, Supine, Non-Supine, and REM Apnea Index and AHI **Graphical presentation of:** • Sleep/wake • Head position • Snoring • Sleep disordered breathing events • Pulse rate with arousal indicators SpO_2	Equivalent. The PoSAS Software reports are similar in content to the ARES predicate device and identical to that of the reference Night Shift software for display of data calculated by Night Shift firmware.

Specification	Proposed Device: PoSAS Software (K172799)	Predicate Device: ARES (K112514)	Discussion Differences
Data Analyzed and Displayed on Report	**Transfer pulse and SpO_2 data file from oximeter via USB and process and analyze data for report.** • Mean SpO_2 • Minutes SpO_2 < 90% • Minutes SpO_2 < 88% • Lowest Desaturation • Mean BPM • Std Dev Pulse • Min Pulse • Max Pulse Events: • SpO_2 3% and 4% desaturation events • SpO_2 3% and 4% desaturation index • Pulse events (6 bpm change) • Pulse Events/hr Overall **Pulse oximeter events combined with Night Shift position:** • Supine SpO_2 3% and 4% desaturation index • Non-supine SpO_2 3% and 4% desaturation index • Pulse Events/hr Supine • Pulse Events/hr Non-supine • SpO_2 Overall/Non-Supine Graphical Presentation: • Pulse • SpO_2 • 3% and 4% desaturation events • Pulse events (6 bpm change)	**Calculated and reported:** • Mean SpO_2 overall, supine, non-supine • % Time SpO_2 Below 95%, 90%, and 85% • Mean nadir for desaturation events	Equivalent. PoSAS analyzes and reports on the SpO_2 and pulse rate signals in the same manner as the ARES. The analysis and reporting of SpO_2 and pulse rate use identical algorithms to the reference Sleep Profiler software. The PoSAS uses the sleeping position from the Night Shift to derive positional-related SpO_2 and Pulse measures.

Specification	Proposed Device: PoSAS Software (K172799)	Predicate Device: ARES (K112514)	Discussion Differences
Detailed Reports	Up to 8 nights of detailed data for Night Shift only reports and Night Shift plus pulse oximeter Reports. Unlimited nights of data for pulse oximeter only reports.	Multi-night reports and test-retest reports	Different. PoSAS and ARES both offer multi-night reports. PoSAS does not offer test-retest comparison statistics.
Number of Hours per Night on Report	Up to 10 hours per night for Night Shift data and up to 12 hours per night for pulse oximeter data.	Up to 8 hours per night.	Equivalent. PoSAS provides reports with a greater number of hours per night than the ARES.
Data Transfer	Data transfer from Night Shift flash storage via USB 2.0. Data transfer from pulse oximeter internal storage via USB 2.0.	Data transfer from ARES Unicorder SD Card via USB 2.0.	Equivalent. The data transfer from for the PoSAS and ARES is USB 2.0. Night Shift data transfer to the PoSAS Software is identical to the Night Shift data transfer to the Night Shift software (reference device). The pulse oximeter transfers data via USB port and Windows OS drivers provided by the manufacturer.
Device Management	Night Shift: • Clear study history • Adjust Feedback settings • Set Date/Time on Device Pulse Oximeter: • Set Date/Time on Device • Clear Study History	• Initialize device (sets the device status, date/time, and writes basic patient identifiers to the device) • Download Patient Date • Format Device (Clear study data)	Equivalent. The ARES software can be used to prepare the ARES recorder for the next study in the same manner the PoSAS Software is used to prepare its input devices for the next study. The PoSAS Software allows for the same settings to be adjusted as the Night Shift software (reference device) with the additional capability of setting the date/time and clearing data from the pulse oximeter, which is similar to the nVision Data Management software (reference device).

Specification	Proposed Device: PoSAS Software (K172799)	Predicate Device: ARES (K112514)	Discussion Differences
Computer requirements	• Processor : Minimum 2.8 GHz • Operating System: Windows 7, 8, or 10 • Windows 64-bit processor • RAM: 2GB • USB port: 2 • PDF Viewing Software • Active and up-to-date anti-virus software and firewalls • Microsoft Visual C++ 2008 SP1 Redistributable Package	• Operating System: Windows • USB Port: 1 • Windows 32-bit or 64-bit processor • Internet Connection • Internet Browser: Internet Explorer • Microsoft .Net 2.0 framework or higher PDF Viewing Software	Different. Two USB ports are required for PoSAS so that the Night Shift and pulse oximeter can be plugged in simultaneously. PoSAS does not require an Internet Connection.
Computer Security	• The person installing the PoSAS Software and pulse oximeter Drivers must have sufficient privileges (i.e. administrator) to install software and drivers. • The software user must have the ability to read and write to the computer's USB ports.	• The person installing the custom files for the web portal must have admin rights. • The software user must have the ability to read and write to the computer's USB ports. • Web-portal software required an account and login.	Equivalent. Admin rights are required for initial installation of both the PoSAS and ARES. Both devices require the user to be able to read-write from the computer's USB ports. PoSAS has a subset of security measures due to being available only as desktop software application.

The Night Shift software (K140190) component provides device management, data transfer, numerical calculations, and reporting of data obtained by the Night Shift Device. The PoSAS Software provides the same device management, data transfer, numerical calculations, and reporting of data obtained by the Night Shift Device as the previously cleared Night Shift software.

The software algorithm used in the Sleep Profiler (K153412) for the processing of pulse oximeter (i.e. SpO2 and pulse rate) data is identical to the algorithms used in the PoSAS software for the processing of pulse oximeter data.

The Nonin nVISION Data Management software (K033307) is the reference device to support data transfer from the pulse oximeter.

PERFORMANCE TESTING

SUMMARY OF NON-CLINICAL TESTS:

Support for the substantial equivalence of the PoSAS Software was provided as a result of risk management and software testing. The subject device is in compliance with ISO 14971:2007, "Medical devices – Application of risk management to medical devices".

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Other relevant FDA guidance documents were also followed, including "General Principles of Software Validation" and "Guidance for Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.

Performance testing of the PoSAS Software was completed to confirm it is accurate and sensitive enough to recognize pulse events and 3%/4% desaturation events. This testing used a Pulse Oximeter Tester to generate patterns of pulse rate and SpO2 changes.

The PoSAS Software has been tested through verification of specifications and system level validation. The results of the verification and validation activities that have been performed demonstrate that the software meets requirements to support substantial equivalence.

Retrospective data from sleep studies acquired with the Advanced Brain Monitoring X8/PSG2 device (K152040, a device used to acquire sleep study data) were analyzed with both PoSAS software and the Sleep Profiler software. FDA's guidance "Guidance for Clinical Investigators, Industry, and FDA Staff Financial Disclosure by Clinical Investigators" was followed. All primary endpoints for agreement between SpO2 and pulse metrics were achieved demonstrating the equivalence of the PoSAS and reference Sleep Profiler software SpO_2 and pulse rate metrics.

CONCLUSION:

The Positional Sleep Assessment System (PoSAS) Software described in this submission is substantially equivalent to the predicate device in respects of device management, data analysis of Pulse rate and SpO2, and reporting. The proposed and predicate devices utilize similar technology, comparable safety and effectiveness features, and are similar in design and construction. The nonclinical and performance data demonstrate that the PoSAS Software accurately recognizes and analyzes both pulse events and 3%/4% desaturation events, and presents position-related metrics equivalently to the predicate device. The PoSAS Software is considered to be substantially equivalent to the predicate device.