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June 23, 2016

Embla Systems
Shane Sawall
Regulatory Affairs Manager
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Kanata, Ontario
Canada K2K 3C7

Re: K153353
Trade/Device Name: Sandman Elite
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLZ
Dated: May 20, 2016
Received: May 24, 2016

Dear Shane Sawall:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Michael J. Hoffmann -A

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

Indications for Use

510(k) Number (if known)

K153353

Device Name

Sandman Elite

Indications for Use (Describe)

The Sandman Elite software is intended for Polysomnography studies on pediatric and adult patients, and allows recording, displaying, analysis, printing and storage of physiological signals to assist in the diagnosis of various sleep disorders. The Sandman software also allows:

- Sleep report templates 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;
- An optional 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.

The Sandman software is intended for use only by qualified and trained medical practitioners in research and clinical environments, who evaluate the software output with their clinical experience and judgment to provide diagnostic conclusions about the patient's condition.

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

Submitted by: Embla Systems
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Date Prepared: June 22, 2016

Proprietary Name: Sandman Elite

Common Name: Polysomnograph software

Classification Name: Automatic Event Detection Software for
Polysomnograph with Electroencephalograph

Product code: OLZ

Device Class: II

Regulation Number: 21 CFR 882.1400

Predicate Device: Sandman (K934599); Natus SleepWorks (K090277)

Description:

1. Overview Sandman Elite Software

The Sandman Elite Application is a software product that runs on a desktop or laptop computer and requires no specialized hardware. It is a Windows based application used at sleep labs by trained clinicians to investigate sleep disorders.

2. Main Applications

The Sandman Elite application collects and digitizes the electrical voltages of patient physiological signals. After collecting and saving the signals, it provides tools and modules to analyze the signals, which aid in the interpretation of a sleep study. The software consists of four main applications:

- **Collection** - Real time collection of EEG and other physiological parameters.
- **Analysis** - Real time analysis of data to identify events which may require special attention from qualified medical professional in attendance.
- **Data Management** - Allows the user to copy, move, back up, and delete collected patient files
- **Configuration** - Allows the user to change configuration settings such as your site information, the media used for file storage and to create and manage user preferences.

The Sandman Elite application also includes a separate independent Report Builder module. The Report Builder is a tool developed to assist the user in creating a customized report. All data are stored either locally or on a remote hard disk (network server). Provisions exist for archiving to several appropriate types of digital media, most frequently CD ROM.

3. Typical work flow using the Sandman Elite Application software

During the Collection 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 modules

The Sandman Elite application software contains a number of computer-assisted scoring modules. All computer assisted-scoring modules are provided to assist trained medical practitioners in the review and analysis of vast amounts of polysomnography data. The computer assisted-scoring modules are for analysis of adult patient data only. Each computer-assisted scoring module runs a specific type of event scoring on the patient file. The scoring rule parameters used in the computer-assisted scoring modules depend on the montage type associated with the study.

The ten computer-assisted scoring modules are:

- Respiratory module
- Desaturation module
- pH module
- ECG module
- Associations module
- EtCO₂ module
- PLM module

- Snoring module
- Bad Data module
- XactTrace module

5. Diagnosis

The Sandman Elite application software is intended for use by qualified and trained medical practitioners in research and clinical environments, who evaluate the software output with their clinical experience and judgement to provide diagnostic conclusions about the patient's condition. The Sandman Elite software does not control the delivery of energy, the administration of drugs, or any form of life sustaining function to the patient.

Indications for Use:

The Sandman Elite software is intended for Polysomnography studies on pediatric and adult patients, and allows recording, displaying, analysis, printing and storage of physiological signals to assist in the diagnosis of various sleep disorders. The Sandman software also allows:

- Sleep report templates 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;
- An optional 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.

The Sandman software is intended for use only by qualified and trained medical practitioners in research and clinical environments, who evaluate the software output with their clinical experience and judgment to provide diagnostic conclusions about the patient's condition.

Comparison to Predicate Device:

	Predicate	Predicate	Subject Device
	Sandman K934599	SleepWorks K090277	Sandman Elite
Device Class	Class II	Class II	Class II
Class Name	Electroencephalograph	Electroencephalograph	Electroencephalograph
Product Code	OLV = Standard Polysomnograph with Electroencephalograph	OLZ = Automatic Event Detection Software for Polysomnograph with	OLZ = Automatic Event Detection Software for Polysomnograph with

	Predicate	Predicate	Subject Device
	Sandman K934599	SleepWorks K090277	Sandman Elite
		Electroencephalograph	Electroencephalograph
Intended User	Medical Professional	Medical Professional	Medical Professional
Indications for Use	<p>The SANDMAN provides paperless digital recording and handling of physiological signals intended for a sleep EEG laboratory.</p>	<p>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.</p> <p>The Sleepworks allows:</p> <p>Automated analysis of physiological signals that is intended for use only in adults.</p> <p>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.</p> <p>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;</p> <p>Sleep Works software does not provide any diagnostic conclusion about the patient's</p>	<p>The Sandman Elite software is intended for Polysomnography studies on pediatric and adult patients, and allows recording, displaying, analysis, printing and storage of physiological signals to assist in the diagnosis of various sleep disorders. The Sandman software also allows:</p> <p>Sleep report templates 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;</p> <p>An optional automated analysis of physiological signals that is intended for use only in adults;</p> <p>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. The Sandman software is</p>

	Predicate	Predicate	Subject Device
	Sandman K934599	SleepWorks K090277	Sandman Elite
		condition and is intended to be used only by qualified and trained medical practitioners; in research and clinical environments.	intended for use only by qualified and trained medical practitioners in research and clinical environments, who evaluate the software output with their clinical experience and judgment to provide diagnostic conclusions about the patient's condition.
User input	Mouse/keyboard	Mouse/keyboard	Mouse/keyboard
Acquire, display, store, and archive PSG data	Yes	Yes	Yes
Signal digitized	Amplifier included as part of the system	By separate proprietary amplifier	By separate proprietary amplifier
Software Modules			
Respiratory event marking	Yes (Manual)	Yes (Manual & Computer Assisted)	Yes (Manual & Computer Assisted)
Sleep staging/scoring	Yes. Manual	Yes. Manual/computer assisted	Yes. Manual
Arousal Event Marking	Yes (Manual)	Yes. Manual/computer assisted	Yes. Manual
Limb movements event marking	Yes (Manual)	Yes (Manual & Computer Assisted)	Yes (Manual & Computer Assisted)
Snore event marking	Yes (Manual)	Yes (Manual & Computer Assisted)	Yes (Manual & Computer Assisted)
Oxygen Desaturation event marking	Yes (Manual)	Yes (Manual & Computer Assisted)	Yes (Manual & Computer Assisted)
Heart Rate data trend & summary	No	Yes (Manual & Computer Assisted)	Yes (Manual & Computer Assisted)
PH data trend and summary	No	Yes (Manual & Computer Assisted)	Yes (Manual & Computer Assisted)
EtCO2 data trend & summary	No	Yes (Manual & Computer Assisted)	Yes (Manual & Computer Assisted)
Associate related events	No	Yes (Manual & Computer Assisted)	Yes (Manual & Computer Assisted)
Flags out range	No	Yes (Manual & Computer	Yes (Manual &

	Predicate	Predicate	Subject Device
	Sandman K934599	SleepWorks K090277	Sandman Elite
data "Bad Data"		Assisted)	Computer Assisted)
Derived Respiratory Traces	No	Yes , Effort Sum, difference, average, Flow Volume Loop	Yes, XactTrace module in Sandman Elite
Synchronized patient video	No	Yes	Yes
Oximetry data display and reporting	Yes	Yes	Yes
Data storage	Local or remote, hard disk	Local or remote, hard disk	Local or remote, hard disk
Audio/ Visual Alerts On Calibrated Channels	No	Yes	Yes
Signals recorded (output)	<ul style="list-style-type: none"> ▪ 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 	<ul style="list-style-type: none"> ▪ 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 	<ul style="list-style-type: none"> ▪ 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

Brief Summary of Performance Tests:

Biocompatibility

The Sandman Elite is a software-only device. Biocompatibility testing is not applicable.

Electrical Safety and EMC

The Sandman Elite is a software-only device. Electrical safety evaluation and EMC evaluation is not applicable.

Software Verification

Testing of the Sandman Elite was performed in compliance with the Natus Medical incorporated design control process. It was found that the Sandman Elite software meets the design specification and performs as specified.

Animal Study

There were no animal studies performed for this submission.

Clinical Study Summary – Respiratory, Limb Movement and Snore Event Assisted-scoring Modules

1.1. Participants

Fifty-six (56) diagnostic PSG sleep studies were collected (one study per patient). All patients involved in this study were adult patients (>18 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: 54 per event evaluated
Total Number of scored Epochs (30 Sec): $\geq 49,704$
Total Number of Hours: ≥ 411.99
Mean number of epochs per subject: ≥ 920.4
Minimum number of epochs per subject: 711
Maximum Number of epochs per subject: 1,147

Data from 54 subjects were evaluated for respiratory, limb movement and snore events. All epochs from these subjects were scored.

1.3. Objective of the study

The goal of the validation study reported here is to establish that Sandman performance is equivalent to the performance of the predicate device. For the purpose of this study "Reference standard" is defined using majority rule, that is, at least two out of three expert scorings (medical professionals certified on PSG recording and analysis) agree on the presence of an event within an 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
- Body position
- Snoring

1.5. PSG analysis protocol

All physiologic data were collected and stored on a Sandman System. The ECG, EEG, EMG, EOG and Snoring channels were sampled at 200 Hz. The Airflow and Chest, abdominal movement channels were sampled at 25 Hz. The Pulse oximetry channel was sampled at 10 Hz. The Body Position channel was sampled at 1 Hz.

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:

- Apnea is scored when both of the following criteria are met:
 - a. There is a drop in the peak signal excursion by $\geq 90\%$ of pre-event baseline respiratory nasal pressure or flow sensor signal.
 - b. The duration of the $\geq 90\%$ drop in sensor signal is ≥ 10 seconds.
- The apnea is Obstructive if it meets apnea criteria and is associated with continued or increased inspiratory effort throughout the entire period of absent airflow.
- The apnea is Central if it meets apnea criteria and is associated with absent inspiratory effort throughout the entire period of absent airflow.
- The apnea is Mixed if it meets apnea criteria and is associated with absent inspiratory effort in the initial portion of the event followed by resumption of inspiratory effort in the second portion of the event.
- Hypopnea is scored if all of the following criteria are met:
 - a. The peak signal excursions drop by $\geq 30\%$ of pre-event baseline using nasal pressure, PAP device flow or alternative hypopnea sensor.
 - b. The duration of the $\geq 30\%$ drop in signal excursion is ≥ 10 seconds.
 - c. There is a $\geq 3\%$ oxygen desaturation from pre-event baseline or the event is associated with an arousal.
- Limb movement is scored if the following significant leg movement (LM) events are indicated:
 - a. The minimum duration of a LM event is 0.5 seconds.
 - b. The maximum duration of a LM event is 10 seconds.
 - c. The minimum amplitude of a LM event is an 8 μV increase in EMG voltage above resting EMG.
- Snore: The scoring of snore events relies on clinical interpretation.

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

- Central apnea
- Obstructive apnea
- Hypopnea

- Limb movement
- Snoring

The Sandman assisted-scoring module default values applied for the clinical study are listed in the following table.

Respiratory Module Default Settings	
Analysis rules	Default Value
Processing window width	120.0 sec
Average number of breaths per minute	15.0
Maximum airflow amplitude for Apnea	26.0%
Maximum airflow amplitude for Hypopnea	70.0%
Minimum SaO2 desaturation drop for Hypopnea	3.00%
Typical delay from the start of a respiratory event to the start of a desaturation	100.00 sec
Minimum duration for a respiratory event	10 sec
Keep user scored/validated events?	Keep
Does the file need to be stage scored before running analysis	Yes
Always assume a respiratory event has an arousal	Do not assume
Analysis Parameters	Default Value
Analysis Range	Entire File (Lights Out to Lights On)
Analysis Channels: Airflow, Chest and Abdomen	None (Applicable channel selected by the user)
Periodic Limb Movement (PLM) Module Default Settings	
Analysis rules	Default Value
Base Amplitude Increase	5.0 μ v
Maximum Event Termination Voltage above baseline	2.0 μ v
Minimum Event Termination Duration	0.5 sec
Minimum Event Length	0.5 sec
Maximum Event Length	10.0 sec
Minimum Event Interval	5.0 sec
Maximum Event Interval	90.0 sec

Maximum Left and Right Interval	5.0 sec
Minimum number of events per Episode	4
Keep user scored/validated events	Keep
Does the file need to be stage scored before running analysis	Yes
Always Assume Events have Arousals	No
Use a Band Pass Filter on the Left Leg?	Yes
Low Frequency for the Left Leg Band Pass Filter	10.0 Hz
High Frequency for the Left Leg Band Pass Filter	100.0 Hz
Use a Band Pass Filter on the Right Leg?	Yes
Low Frequency for the Right Leg Band Pass Filter	10.0 Hz
High Frequency for the Right Leg Band Pass Filter	100.0 Hz
Use a Band Pass Filter on Combined Legs?	Yes
Low Frequency for Combined Legs Band Pass Filter	10.0 Hz
High Frequency for Combined Legs Band Pass Filter	100.0 Hz
Use a Notch Filter on the Left Leg?	No
Use a Notch Filter on the Right Leg?	No
Use a Notch Filter on Combined Legs?	No
Frequency for the Notch Filter	60.0 HZ
Analysis Parameters	Default Value
Analysis Time Range	Entire File (Lights Out to Lights On)
Analysis Channels: Left Leg, Reference Channel for Left Leg Right Leg, Reference Channel for Right Leg Combined Legs Referenced Channel for Combined Legs	None (Applicable channel selected by the user)
Snore Module Default Settings	
Analysis rules	Default Value
Snoring Sensitivity	4.0 x
Percentage above Baseline (Fine Adjustment)	350.0 %
Minimum Event Length	0.5 sec

Maximum Event Length	5.0 sec
Keep user scored/validated events	Keep
Does the file need to be stage scored before running analysis	Yes
Use a Software Notch Filter	No
Frequency of Notch Filter	60 Hz
Use a Band Pass filter of Snore Channel	Yes
Low Frequency for the Snore channel Band Pass Filter	10.0 Hz
High Frequency for the Snore channel Band Pass Filter	100.0 Hz
Analysis Parameters	Default Value
Analysis Time Range	Entire File (Lights Out to Lights On)
Analysis Channels: Snore	Automatic (User applied Snore#2)

PLEASE NOTE: Performance results reported here were obtained using default parameters for the assisted-scoring modules evaluated. Performance of the Sandman assisted scoring modules at settings different than the noted Default Values have not been validated and may result in performance different than reported here.

1.6. Outcomes

Positive Percent Agreement (PPA) between Sandman assisted-scoring modules 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 Sandman Event Detection Assisted Scoring Modules

Event	PPA			False Detection Rate Per Hour		
	Mean	95% CI		Mean	95% CI	
		Lower	Upper		Lower	Upper
Central apnea	95.1%	88.1%	97.4%	3.8	2.4	6.4
Mixed apnea	97.6%	88.7%	99.5%	0.8	0.4	1.4
Obstructive apnea	92.0%	86.0%	94.1%	7.7	6.1	9.6
Hypopnea	85.9%	79.8%	88.2%	15.4	13.3	17.8
Limb movement	86.0%	83.0%	88.5%	16.8	14.0	20.5
Snoring	82.0%	78.3%	84.7%	21.6	18.3	26.0

1.7. Clinical Study Conclusion

Compared to the Reference standard, Sandman 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 Sandman Elite 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 Sandman Elite device should perform as intended in the specified use conditions. The clinical validation of the computer-assisted scoring modules demonstrates that the Sandman Elite device performs comparably to the predicate device that is currently marketed for the same intended use.