DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 11, 2017

Embla Systems
Shane Sawall
Regulatory Affairs Manager
1 Hines Road Suite 202
Kanata, Ontario, CA K2K 3C7

Re: K163617
Trade/Device Name: REMbrandt
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLZ
Dated: March 8, 2017
Received: March 10, 2017

Dear Mr. 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,

Michael J. Hoffmann -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163617

Device Name
REMbrandt

Indications for Use *(Describe)*
The REMbrandt software is intended for Polysomnography studies and 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 REMbrandt 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 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;

The REMbrandt 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.

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)

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510(K) Summary

Submitted by: Embla Systems
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Contact Person: Shane Sawall
Regulatory Affairs Manager
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Date Prepared: March 8, 2017

Proprietary Name: REMbrandt

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: Natus SleepWorks K090277 (primary), REMbrandt K962865

Description:

1. Overview REMbrandt Software

The REMbrandt software consists of three applications, DataLab, Analysis Manager and REMbrandt Manager, which run on a desktop or laptop computer and require no specialized hardware. They are Windows based applications used by trained medical professionals to investigate sleep disorders.

2. Main Functional Areas

The REMbrandt software collects and digitizes the electrical voltages of patient physiological signals. After collecting and saving the signals, it provides tools and detectors to analyze the signals, which aid in the interpretation of a sleep study. The software consists of four main functional areas:

A. Data Acquisition & Display (REMbrandt DataLab)

B. Scoring/Review & Analysis (REMbrandt Analysis Manager)
C. Report Generation (REMbrandt Analysis Manager)
D. Archiving & Data Management (REMbrandt Manager)

Data Acquisition & Display:
The REMbrandt DataLab application collects and displays continuous physiological waveform data (via a digital polysomnography amplifier), and digital audio/video (via standard audio/video equipment). The data is stored and displayed in real time by the REMbrandt DataLab software on the acquisition computer and made available for subsequent review and scoring by a sleep technologist followed by review and interpretation by a certified sleep medicine physician.

Study Scoring/Review & Analysis:
The REMbrandt Analysis Manager application has features that facilitate study navigation, event marking, sleep stage scoring, review of synchronized digital video, and data trends required by medical professionals in order to properly analyze and interpret sleep study data. (See figure 1). In addition to allowing users to manually mark sleep events including Arousals, Respiratory Events (Apnea & Hypopnea), Oxygen Desaturations, Limb Movements, Snoring and sleep stages, the REMbrandt software also optionally provides computer assisted event marking analyzers for a subset of these events as well as analyzers that summarize digital data in data ranges.

Computer-assisted scoring modules:
The REMbrandt software contains eight (8) computer-assisted scoring analyzers. 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 scoring 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 scoring rule parameters used in the computer-assisted scoring analyzers depend on available input signals in the study as well as user defined settings. All output from computer assisted scoring analyzers require medical professional review and acceptance.

The computer-assisted scoring analyzers are as follows:

- Apnea/Hypopnea Detector: Marks potential Apneas & Hypopnea events.
- Limb Movement Detector: Marks potential limb movement events
- Arousal Detector: Marks arousal events on EEG traces
- Snore Detector: Marks potential snore events
- Desaturation Detector: Marks drops in oxygen saturation based on user set threshold CO2 Analyzer: Summarizes CO2 data recorded from a third party Capnograph device.

- Heart Rate Detector: Indicates heart rate by processing EKG waveform and shows Heart Rate values; marks tachy-bradycardia events based on heart rate value thresholds that are user configurable.
- Body Position Detector: Converts DC inputs or values from gravity xy based position sensor into the body positions tagged in sleep studies (Upright, Supine, Left, Right, Prone and Unknown).
- Pulse Transit Time (PTT) Trace Generator: Derived calculation of pulse transit time (PTT) which is a measure of time difference between the ECG R top and the peak of the pleth waveform from a pulse oximeter.

Report Generation:
Once the digital polysomnography data has been acquired scored and reviewed by both a polysomnographic technologist and a sleep physician the REMbrandt software is used to generate a summary report of the sleep study which includes summary statistics of sleep staging describing the patients sleep architecture, summary of sleep events including maximum, minimum counts, indexes, duration, and range based data as well as graphical representations of each (trends). The generated sleep reports are part of the digital polysomnograph and the REMbrandt software also includes tools to customize report templates to conform to individual sleep center standards/policies and graphic norms.

Archiving & Data Management:
All data are stored either locally or on a remote hard disk (network server) Provisions exist for archiving to several appropriate types of digital storage. REMbrandt Manager also allows the user to copy, move, back up, and delete collected studies.

3. Diagnosis

The REMbrandt 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. REMbrandt 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 REMbrandt 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 REMbrandt software is intended for Polysomnography studies and 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 REMbrandt 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 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;

The REMbrandt software does not provide any diagnostic conclusions 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 Device:

	Predicate	**Predicate**	**Subject Device**
	Rembrandt K962865	***SleepWorks K090277***	***REMbrandt***
Device Class	Class II	Class II	Class II
Class Name	Apnea Monitor	Electroencephalograph	Electroencephalograph
Product Code	FLS = Monitor (Apnea Detector), Ventilatory Effort	OLZ = Automatic Event Detection Software for Polysomnograph with Electroencephalograph	Same as SleepWorks
Intended User	Medical Professional	Medical Professional	Medical Professional

Indications for Use	The Medcare Rembrandt System is a physiological signal recorder intended for use in sleep Laboratories. It is used as a paperless polygraph, collecting raw data. It is used to manually analyze the recorded data. The user may manually tag sleep stages, arousals, apnea and hypopnea and Periodic Leg Movement. The Rembrandt System processes the manual scoring to generate Summary Reports. A polysomnographer would typically review the recorded signals. The Rembrandt System by Medcare Automation does not provide any indications during recording. It does not do any analysis, monitoring or diagnosis of the patient. It does not issue any alarms.	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 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	The REMbrandt software is intended for Polysomnography studies and 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 REMbrandt 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 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; The REMbrandt software does not provide any diagnostic conclusion about the patient's condition and is intended to be used only by qualified and trained medical

		qualified and trained medical practitioners; in research and clinical environments.	practitioners, in research and clinical environments.
User input	Mouse/keyboard	Mouse/keyboard	Mouse/keyboard
Acquire, display, store, and archive PSG data	Yes (post acquisition analysis only)	Yes (post acquisition and real-time analysis	Yes (post acquisition and real-time analysis)
Signal digitized	Amplifier included as part of the system	By separate proprietary amplifier	By separate proprietary amplifier
FFT Analysis (Spectral analysis on any digitized channel	Yes	Yes	Yes
Software Detectors			
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 & Computer Assisted)
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 (including Heart Rate Variability)	No	Yes	Yes
CO2 data trend & summary	No	Yes	Yes
Associate related events	No	Yes (Manual & Computer Assisted)	Yes (Manual & Computer Assisted)
Derived respiratory traces	No	Yes, Effort Sum, difference, average, Flow Volume Loop	Yes, XactTrace module cleared to market via K162140
Synchronized patient video	Yes	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)	▪ 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 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
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

REMbrandt also includes derived calculation of pulse transit time (PTT) which is a measure of time difference between the ECG R top and the peak of the pleth waveform from the pulse oximeter. The reference predicate for this feature of REMbrandt is K142988 Sleepware G3.

Brief Summary of Performance Tests:

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

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

Software Verification
Testing of the REMbrandt was performed in compliance with the Natus Medical incorporated design control process. It was found that the REMbrandt 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 Detectors

1.1. Participants
Fifty (50) diagnostic PSG sleep studies were collected (one study per subject). All subjects involved in this study were adult (>18 years old) subjects with a clinical indication for a sleep study. The subject data were de-identified and applied as subject data to this study.

1.2. Dataset description
Total Number of Subjects: 50 per event evaluated
Total Number of scored Epochs (30 Sec): $\geq$ 45,074
Total Number of Hours: 375:37:00
Mean number of epochs per subject: $\geq$903.5
Minimum number of epochs per subject: 698
Maximum number of epochs per subject: 1078

Data from 50 subjects were evaluated for respiratory, arousal, 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 REMbrandt 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 (SpO_2) and pulse rate
- Body position
- Snoring

1.5. PSG analysis protocol

All physiologic data were collected and stored on a REMbrandt 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 $\geq$ 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 $\geq$ 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

- Arousals: Score arousals during sleep stages (N1, N2, N3 or R) if there is an abrupt shift of EEG frequency including alpha, theta and/or frequencies greater than 16 Hz (but not spindles) that lasts at least 3 seconds, with at least 10 seconds of stable sleep preceding the change. Scoring of arousal in REM requires a concurrent increase in submental EMG lasting at least 1 second.

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

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

1.6. Outcomes

Positive Percent Agreement (PPA) between REMbrandt assisted-scoring detectors 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 detectors are shown in the following table.

PPA and False Detection Rate Per Hour of REMbrandt Event Detection Assisted Scoring Detectors

	REMbrandt			
	PPA		FD/h	
Event	Mean	95% CI	Mean	95% CI
Central Apnea	99%	98.3% to 99.4%	0.7	0.4 to 1.5
Mixed Apnea	99.5%	98.6% to 99.8%	0.3	0.1 to 0.7
Obstructive Apnea	98%	96.6% to 98.7%	1.6	1.0 to 3.0
Hypopnea	90.4%	87.9% to 92.1%	4.0	3.2 to 5.1
Arousal	87.6%	84.3% to 89.6%	9.6	7.2 to 13.4
Limb Movement	88.7%	86.0% to 91.0%	11.1	8.5 to 14.6
Snore	87.1%	84.1% to 89.5%	12.3	9.5 to 16.2

1.7. Clinical Study Conclusion

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