DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 1, 2016

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

Re: K162140
Trade/Device Name: RemLogic
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLZ
Dated: November 1, 2016
Received: November 2, 2016

Dear Shane T. 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 -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

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)*
K162140

Device Name
RemLogic

Indications for Use *(Describe)*
The RemLogic 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 RemLogic 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 RemLogic 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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: Oct. 31, 2016

Proprietary Name: RemLogic

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: Embla (K971813); Natus SleepWorks (K090277) - primary

Description:

1. Overview RemLogic Software

The RemLogic 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 by trained medical professionals to investigate sleep disorders.

2. Main Functional Areas

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

- **Acquisition** - Real time collection of EEG and other physiological parameters.

- **Scoring & Review** - Includes functions providing the user with tools to quickly review PSG studies, either during real time collection of data or after the recordings are complete

- **Reports** - Once the digital polysomnography data has been acquired scored and reviewed by both a polysomnographic technologist and a sleep physician the RemLogic 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 polysomnography and the RemLogic software also includes tools to customize report templates to conform to individual sleep center standards/policies and graphic norms.

3. Typical work flow using the RemLogic 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

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

The eight computer-assisted scoring analyzers are:
• Arousal Analyzer
• Respiratory Analyzer
• Limb Movement Analyzer
• Snoring Analyzer
• Desaturation Analyzer
• Heart Rate Analyzer
• Associations Analyzer
• XactTrace module

5. Diagnosis

The RemLogic 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 RemLogic 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 RemLogic 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 RemLogic software also 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 RemLogic 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**
	Embla K971813	***SleepWorks K090277***	***RemLogic***
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 Electroencephalograph	Same as SleepWorks
Intended User	Medical Professional	Medical Professional	Medical Professional

Indications for Use	Embla is a polysomnographic system that is intended to record, display, and print EEG and other physiological information to clinicians/physicians. The device will be used in hospitals, institutions, sleep centers or clinics, or other test environments where patients require documentation of various sleep or other physiologic disorders.	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 RemLogic 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 RemLogic 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 RemLogic 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	Yes	Yes
Signal digitized	Amplifier included as part of the system	By separate proprietary amplifier	By separate proprietary amplifier
Software Analyzers			
Respiratory event marking	Yes (Manual & Computer Assisted for apneas only)	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 (Manual & Computer Assisted)	Yes (Manual & Computer Assisted)
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 and Flattening Index; cleared to market via K041724
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)	▪ 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

RemLogic 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 RemLogic is K142988 Sleepware G3.

Brief Summary of Performance Tests:

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

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

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

1.1. Participants
Fifty-one (51) 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: 51 per event evaluated
Total Number of scored Epochs (30 Sec): $\geq$ 47,113
Total Number of Hours: 392:36:30
Average number of epochs per subject: 924
Minimum number of epochs per subject: 764

Data from 51 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 RemLogic 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 RemLogic 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 ≥ 90% of pre-event baseline respiratory nasal pressure or flow sensor signal.
  b. The duration of the ≥ 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 ≥ 30% of pre-event baseline using nasal pressure, PAP device flow or alternative hypopnea sensor.
  b. The duration of the ≥ 30% drop in signal excursion is ≥ 10 seconds.
  c. There is a ≥ 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 in the EEG frequency that lasts at least 3 seconds (exclude sleep spindles) with at least 10 seconds of stable sleep preceding the change. Scoring arousals in REM requires a concurrent increase in Chin EMG lasting at least 1 second.

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

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

1.6. Outcomes

Positive Percent Agreement (PPA) between RemLogic 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 analyzers are shown in the following table.

PPA and False Detection Rate Per Hour of RemLogic Event Detection Assisted Scoring Analyzers

	RemLogic			
	PPA		FD/h	
Event	Mean	95% CI	Mean	95% CI
Central Apnea	98%	96% to 99%	2.1	1.2 to 4.1
Mixed Apnea	98%	96% to 99%	2.4	1.3 to 5.1
Obstructive Apnea	94%	91% to 95%	7.8	5.6 to 10.9
Hypopnea	86%	83% to 87%	17.4	15.0 to 20.0
Arousal	83%	81% to 85%	20.2	17.8 to 22.6
Limb Movement	86%	84% to 88%	16.8	14.0 to 19.9
Snore	85%	83% to 88%	17.8	14.9 to 20.9

1.7. Clinical Study Conclusion

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