January 17, 2019

Neurozone MSH Incorporated
Daniel Rodriguez
Senior Manager QA/RA
17 Lantern Lane
Dundas, L9H 6N9 CA

Re: K182227
Trade/Device Name: Esprit Nova
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLZ
Dated: November 3, 2018
Received: December 18, 2018

Dear Daniel Rodriguez:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jay R. Gupta -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K182227

Device Name
EspiritNova

Indications for Use *(Describe)*
Esprit Nova is a software-only product intended to assist a physician in the diagnostic evaluation of sleep quality and sleep disordered breathing in adults only. Esprit Nova analyzes the physiological signals and automatically scores sleep events; including the stages of sleep, microarousals, snoring, periodic limb movements, desaturations and sleep disordered breathing events apneas, hypopneas, and respiratory event related arousals). This device is to be used under the supervision of a physician. The device does not provide any diagnostic conclusion 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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510K Summary

Date: November 3rd., 2018

Submitted by: Neurozone MSH Incorporated
17 Lantern Lane
Dundas, Ontario
Canada L9H 6N9

Contact Person:

Daniel Ramirez
Senior Manager, Quality Assurance and Regulatory Affairs
Neurozone MSH Incorporated
Tel.: 2892389696
E-mail: daniel.ramirez@neurozonemsh.com

Propietary Name: EspritNova

Common Name: EspritNova

Classification Name: 882.1400 Electroencephalograph, Automatic Event Detection Software For Polysomnograph With Electroencephalograph
Product code: OLZ
Device Class: II

Predicate Devices: Sleep Profiler (K153412)
Sandman Elite (for the Limb Movement detector only) (K153353)

Description

Esprit Nova is a software application that analyzes previously recorded physiological signals obtained during sleep. The software can analyze any EDF files acquired with Trackit SleepWalker (K010460) Compumedics Somté PSG System(K072201) and/or Sandman (K040113). Automated algorithms are applied to the raw signals to interpret the raw signal information. The software automates recognition of:

- Sleep stages Rapid Eye Movement (REM), nREM (N1, N2, N3) and wake
- Heart rate
- Snoring
- Sleep/wake
- Body position
- Arousals
- EEG, ECG, EOG, EMG waveforms
- SaO2

- Airflow
- Respiratory Effort
- Apneas and Hypopneas
- Oxygen desaturations.
- Limb movements

The software identifies and rejects periods with poor electroencephalography signal quality.
The output of the device is a comprehensive sleep study report. Medical and history information can be entered from a questionnaire. The automated analysis of physiological data is integrated with the questionnaire data, medical and history information and included in the report. The Esprit Nova analysis module is hosted on a central server, while the administrative module is a stand-alone application for use on Microsoft Windows 7 (or higher) operating system platforms. The administrative module works as a local database to keep records of patients' and to transmit data back and forth to the central server.

Indications for Use

Esprit Nova is a software-only product intended to assist a physician in the diagnostic evaluation of sleep quality and sleep disordered breathing in adults only. Esprit Nova analyzes the physiological signals and automatically scores sleep events; including the stages of sleep, microarousals, snoring, periodic limb movements, desaturations and sleep disordered breathing events apneas, hypopneas, and respiratory event related arousals).
This device is to be used under the supervision of a physician.
The device does not provide any diagnostic conclusion about the patient's condition.

Predicate Comparison

The substantial equivalence of the Esprit Nova device is based on its similarities to the cleared SleepProfiler (K153412).

Device Feature	Subject Device Esprit Nova	Predicate Sleep Profiler (K153412)
Classification	Class II, OLZ, Automated Event Detection Software for Polysomnograph with Electroencephalograph	Class II, OLZ, Automated Event Detection Software for Polysomnograph with Electroencephalograph
Intended Use		
Purpose and function:	Sleep monitoring	Sleep monitoring
Patient population	Adult	Adult
Environment of use (data acquisition)	Clinic, home	Clinic, home
Intended User	qualified medical practitioners	qualified medical practitioners
Signal Processing		
Input Signal	EEG, EOG, ECG, oximetry, airflow, effort, EMG.	EEG, heart rate, oximetry, airflow.
Number of Electrodes and location	M1, M2, Fpz and ground.	2 active (Fp1-Fp2) + Ground.

Device Feature	Subject Device Esprit Nova	Predicate Sleep Profiler (K153412)
Parameters		
Parameters	° Sleep stages Rapid Eye Movement (REM) and nREM (N1, N2, N3) and wake ° Heart rate (trend and summary table) ° Snoring count/index ° Sleep/wake ° body position (trend) ° Arousals ° EEG,ECG,EOG, EMG waveforms ° SaO2 ° Airflow ° Respiratory Effort ° Apneas and Hypopneas ° Oxygen desaturations	° Sleep stages Rapid Eye Movement (REM) and nREM (N1, N2, N3) and wake ° Heart/pulse rate ° Snoring loudness ° Sleep/wake ° Head movement and position ° Arousals ° ECG,EOG, EMG waveform ° SpO2 ° Airflow ° Respiratory Effort ° Apneas and Hypopneas ° Oxygen desaturations.
Signal quality	Rejects bad signal quality in all signals	Auto-rejects bad signal quality in EEG with optional airflow and SpO2.
Sleep Measures	° Sleep latency ° Total sleep and recording times ° Sleep efficiency ° % time by sleep stage ° Awakenings per hour ° Wake after sleep onset ° REM latency	° Sleep, REM and N3 onset ° Total sleep and recording times ° Sleep efficiency ° % time by sleep stage ° Awakenings per hour ° Wake after sleep onset

Device Feature	Subject Device Esprit Nova	Predicate Sleep Profiler (K153412)
Sleep Staging	Wake (W), REM (R), NREM stage 1 (N1), NREM stage 2 (N2) and slow wave sleep (N3, includes both stages 3 and 4)	Based on one forehead EEG signals to differentiate Wake (W), REM (R), NREM stage 1 (N1), NREM stage 2 (N2) and slow wave sleep (N3, includes both stages 3 and 4)
Sleep Disordered Breathing	° Detects apneas with airflow. Classifies as central apnea (CA), obstructive apnea (OA), mixed apnea (MA). ° Detects hypopneas with airflow signal in conjunction with microarousals and desatrations ° Detects RERA with airflow cortical arousals and effort according to the AASM definition.	° Detects apneas with airflow signal. Each apnea is classified as obstructive but can be edited to be central or mixed apneas. ° Detects hypopneas with airflow signal. Changes in SpO2 are used to determine hypopnea severity (i.e., 4% or 3% events). ° Detects RERAs with airflow signal and cortical arousals (i.e., hypopneas that do not meet the desaturation criteria)
Snoring	From flow, calibrated with Sound Meter.	From microphone 40 dB @ 3% of dynamic range (min) 70 dB @ 90% of dynamic range (max) Accuracy 0.2 dB at mid range.
Usability		
User Editing	Not allowed	Allowed

Device Feature	Subject Device Esprit Nova	Predicate Sleep Profiler (K153412)
Reports	° Graphic, narrative and patient Hx ° Record time ° Sleep time ° Valid sleep time ° Sleep latency (onset) ° Sleep efficiency ° Sleep times and %time per sleep stage ° Sleep stage graph by EEG ° Arousal graph ° arousal classification (spontaneous, limb movement, respiratory) ° Pulse rate graph with autonomic activations. ° Snoring count and index ° Body position graph ° Excluded EEG data ° Medical history ° Disease management comments ° Physician review and signature. ° AHI, numerical and graphical, supine and non-supine ° RDI, numerical and graphical, supine and non-supine. ° #Apneas (OA, CA, MA) ° #Hypopneas (OH< CH) ° #RERAs Mean SpO2, %time < 90 and < 88% SpO2	Graphic, narrative and patient Hx ° Record time ° Sleep time ° Valid sleep time ° Sleep latency (onset) ° Sleep efficiency ° Sleep times and %time per sleep stage ° Sleep stage graph by EEG with cortical arousals. ° Pulse rate graph with autonomic activations. ° Snoring level graph with snoring arousals ° %time snoring > 30, 40, 50 and 60 dB ° Head movement graph with behavioral arousals ° Head position graph ° Excluded EEG data ° Medical history ° Disease management comments ° Physician review and signature. ° AHI, numerical and graphical, supine and non-supine ° RDI, numerical and graphical, supine and non-supine. ° #Apneas ° #Hypopneas ° #RERAs ° Mean SpO2, %time < 90 and < 88% SpO2

Device Feature	Subject Device Esprit Nova	Predicate Sleep Profiler (K153412)
Compatibility	PC Intel Core i3 with Windows 7. hard drive: 1TB monitor: minimum resolution 1024x768 graphics: generic graphics cards supporting the above monitor.	PC with Windows XP operating system and at least 2 GB of RAM.

Device Feature	Subject Device Esprit Nova	Predicate Sleep Profiler (K153412)
Web interface	° processor: Intel Core i3 or better ° hard drive: 1TB or higher ° monitor: minimum resolution 1024x768 ° graphics: generic graphics cards supporting the above monitor ° OS: Microsoft Windows 7 or higher connection to the Internet is required.	**Processor :** ° Minimum 2.8 GHz. Operating System: Windows XP or 7. Java version 6 or greater ° RAM: 1GB ° USB port: 1 ° Internet connection: constant ° Web browser: Internet ° Explorer, or Firefox **Virtual server:** ° Processor: > 2 Ghz ° Operating system: Win Server 2008. ° RAM: > 2GB ° Certificates: Signed ° SSL ° .NET framework: version 2.0 – web server ° version 3.5 processing server ° or Win Server 2008 ° Database: SQL server 2005 **Physical server:** ° Processor: > 2 Ghz ° Operating system: Win Server 2008 ° Enterprise edition (for virtual servers). ° RAM: > 2GB
Performance (Positive/Negative % Agreement)		
Wake	0.83/0.94	0.73/0.94
N1	0.29/0.92	0.25/0.93
N2	0.82/0.80	0.77/0.84

Device Feature	Subject Device Esprit Nova	Predicate Sleep Profiler (K153412)
N3	0.66/0.96	0.76/0.94
REM	0.84/0.97	0.74/0.97

IFU Comparison

Esprit Nova	Sleep Profiler (K153412)
Esprit Nova is a software-only product intended to assist a physician in the diagnostic evaluation of sleep quality and sleep disordered breathing in adults only. Esprit Nova analyzes the physiological signals and automatically scores sleep events; including the stages of sleep, microarousals, snoring, periodic limb movements, desaturations and sleep disordered breathing events apneas, hypopneas, and respiratory event related arousals). This device is to be used under the supervision of a physician. The device does not provide any diagnostic conclusion about the patient's condition.	Sleep Profiler is intended for use for the diagnostic evaluation by a physician to assess sleep quality and score sleep disordered breathing events in adults only. The Sleep Profiler is a software-only device to be used under the supervision of a clinician to analyze physiological signals and automatically score sleep study results; including the staging of sleep, detection of arousals, snoring and sleep disordered breathing events (obstructive apneas, hypopneas and respiratory event related arousals). Central and mixed apneas can be manually marked within the records.

Esprit Nova and the predicate Sleep Profiler are both. Software only products intended. For the assessment of sleep quality and sleep disordered breathing. Both devices are intended to be use in the adult population only and both of the devices incorporate analysis algorithms that automatically detect and mark sleep events including the stages of sleep, detection of arousals, apneas, hypopneas and desaturations as well as snoring events. Both devices are prescription only and are to be used by qualified medical practitioners.

The proposed Esprit Nova device has similar indications for use and uses the same fundamental technology as the legally marketed predicate device, Sleep Profiler (K153412). There are no major differences between the subject and predicate device. Both devices have almost identical IFU.

Both devices provide users with a similar set of sleep quality measures as determine by the American Academy for Sleep Medicine. They (subject and predicate devices) also detect other parameters as arousals, apneas and oxygen desaturations. Both devices offer users a narrative sleep report that summarizes information in the form of graphs and tables, as well as patient medical history as entered by the qualified user

As demonstrated by the results of the clinical validation when compared to a panel of 3 electrophysiologists scoring studies as done in their daily practice (i.e gold standard) Esprit Nova was

found to perform equivalently to the gold standard. Furthermore, Esprit Nova performance is equivalent to the reported performance of the predicate device.

Substantial Equivalence of the Periodic Leg Movement detector

For the Periodic Leg Movement detector we claim substantial equivalence to the Periodic Limb Movement Module of the Sandman Elite (K153353).

Device Feature	Predicate device Sandman Elite (K153353)	Subject device Esprit Nova (K182227)	Comment
Base Amplitude Increase	5.0 µv	5.0 µv	Same
Maximum Event Termination Voltage above baseline	2.0 µv	2.0 µv	Same
Minimum Event Termination Duration	0.5 sec	0.5 sec	Same
Minimum Event Length	0.5 sec	0.5 sec	Same
Maximum Event Length	10.0 sec	10.0 sec	Same
Minimum Event Interval	5.0 sec	5.0 sec	Same
Maximum Event Interval	90.0 sec	90.0 sec	Same
Maximum Left and Right Interval	5.0 sec	5.0 sec	Same
Minimum number of events per Episode	4	4	Same
stage scored before analysis?	Yes	Yes	Same
Use a Band Pass Filter on both Legs?	Yes	Yes	Same
Low Frequency for both legs Band Pass Filter	10.0 Hz	10.0 Hz	Same
High Frequency both legs Band Pass Filter	100.0 Hz	100.0 Hz	Same
Analysis Channels:	Left and right legs	Left and right legs	Same
Positive Percent Agreement **(95% CI)**	86 (83 – 88.5)	87 (83 – 93)	Equivalent
False detection/h	16.8 (14 – 20.5)	2.4 (1.8 – 3.0)	Equivalent

In both devices the Periodic Leg Movement detector (PLM) has identical parameters. Performance of the PLM detector implemented in Esprit Nova is also equivalent to performance of the PLM module of the predicate device as demonstrated by the results of the clinical test.

Brief Summary of Non-Clinical and Clinical Performance Tests

All functionalities and performance of the Esprit Nova algorithm have been verified and validated through bench and clinical performance tests according to the intended use and user of the device.

Non-Clinical: The Esprit Nova device is compliant with all currently accepted safety standards for medical devices of its class which was demonstrated through testing, verification and validation of all components.

Clinical: We conducted an extensive clinical test to: 1) Evaluate the positive and negative percent agreement of Esprit Nova, and to 2) Demonstrate equivalence of the performance, in terms of positive and negative percent agreement of the Esprit Nova algorithm as compared to sleep study assessment by a panel of 3 EEG board certified medical professionals (gold standard).

EspritNova Clinical Validation

Dataset Description:

AGE (Mean ± SD)	44 ± 2.02
GENDER (Female/Male)	24/36

The sample included 60 PSG studies from adult patients that were seen at a Sleep Clinic. 40 studies corresponded with patients with varying degrees of Obstructive Sleep Apnea (OSA, from severe to mild), 4 studies for Restless Legs Syndrome (3 of which also had OSA) seven Titration studies and 9 normal studies.

Diagnosis	# of cases
Obstructive Sleep Apnea	40 { Severe-12 Moderate-14 Mild-14 }
Restless Legs Syndrome	1
Restless Legs Syndrome + OSA	3
Titration	7
Normal	9

Results & Discussion

Algorithm Performance Comparison

		Epochs assigned by Esprit Nova						% agreement (95% CI)*	
		Wake	N1	N2	N3	REM	Total	positive	negative
Epochs assign by expert scoring	Wake	8011	880	359	1	114	9365	**0.83** (0.80-0.86)	**0.94** (0.92-0.95)
	N1	916	1452	2342	27	429	5166	**0.29** (0.26-0.34)	**0.92** (0.91-0.94
	N2	492	1504	15880	1193	376	19445	**0.82** (0.79-0.85)	**0.80** (0.76-0.83)
	N3	24	5	1499	3990	1	5059	**0.66** (0.56-0.76)	**0.96** (0.95-0.98)
	REM	313	346	234	1	5059	5953	**0.84** (0.81-0.88)	**0.97** (0.95-0.98)
	Total	9756	4187	20314	5212	5979	45448		

*Bootstrap 95% Confidence Interval

Esprit Nova performed similar to the qualified medical professionals. The device exhibited better performance in the detection of Wake/REM with higher PPA (83%/84%) and poorer performance in the detection of N1 followed by N3, as was the case for the professional reviewers. While the device achieved only 29% PPA (with a 39% as the higher boundary for the 95% bootstrap Confidence Interval) this is not only equivalent to the behaviour described for medical professionals for N1 detection. Although direct comparison to the predicate is not possible, it is a reasonable approximation considering that the evaluation methodology and the population were similar in both studies. As for the medical experts, Negative percent agreement of Esprit Nova was always above 80% and reached levels as high as 97%.

No complications or adverse events were reported as a consequence of usage of Esprit Nova.

Periodic Leg Movement (PLM) Detector Performance

	Sandman Elite (K153353)	Esprit Nova (K182227)	Professional Reviewers
PPA (95% CI)	86 (83 – 88.5)	87 (83 – 93)	97 (96 – 99)
False detection rate/hour	16.8 (14 – 20.5)	2.4 (1.8 – 3.0)	1.7 (1.3 – 2.3)

The table above shows performance of the Esprit Nova PLM detector compared to a similar detector implemented on a predicate device and mean performance across all 3 professional reviewers. As can be seen, Esprit Nova PLM detector performs very similar to qualified professionals and also to the predicate device and even better False Detection rate.

Conclusions

We believe that given the equivalence of all technological characteristics of the subject device there are no questions of safety or effectiveness of the device. Based on the rationale discussed above we believe that Esprit Nova is substantially equivalent to the predicate Sleep Profiler(K153412). The

Periodic Leg Movement detector Esprit Nova is substantially equivalent to the Periodic Leg Movement detector of the Sandman Elite (K153353).