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

March 14, 2016

Advanced Brain Monitoring, Inc.
℅ Adrienne Lenz
Member
Pathway Regulatory Consulting, LLC
W324 S3649 County Road E
Dousman, Wisconsin 53118

Re: K153412
    Trade/Device Name: Sleep Profiler
    Regulation Number: 21 CFR 882.1400
    Regulation Name: Electroencephalograph
    Regulatory Class: Class II
    Product Code: OLZ
    Dated: February 9, 2016
    Received: February 11, 2016

Dear Adrienne Lenz:

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)*
K153412

Device Name
Sleep Profiler

Indications for Use *(Describe)*

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.

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.

510(k) Summary

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

DATE: March 11, 2016

SUBMITTER:

Advanced Brain Monitoring
2237 Faraday Avenue, Suite 100
Carlsbad, CA 92008
T 760.720.0099
F 760.720.3337

PRIMARY CONTACT PERSON:

Adrienne Lenz, RAC
Member
Pathway Regulatory Consulting, LLC
T 262-290-0023

SECONDARY CONTACT PERSON:

Dan Levendowski
President and Co-founder
Advanced Brain Monitoring, Inc.

DEVICE:

TRADE NAME: Sleep Profiler

COMMON/USUAL NAME: Sleep Profiler

CLASSIFICATION NAMES: 882.1400 Electroencephalograph, Automatic Event Detection Software For Polysomnograph With Electroencephalograph

REVIEW PANEL: Neurology

PRODUCT CODE: OLZ

PREDICATE DEVICE(S):

Sleep Profiler (K130007)

Reference predicate device, Apnea Risk Evaluation System (ARES), Model 610 (K112514)

DEVICE DESCRIPTION:

The Sleep Profiler is a software application that analyzes previously recorded physiological signals obtained during sleep. The Sleep Profiler software can analyze any EDF files acquired with the Advanced Brain Monitoring X4 System and the X8 System models SP40 and SP29.

Automated algorithms are applied to the raw signals in order to derive additional signals and interpret the raw and derived signal information. The software automates recognition of:

- Sleep stages Rapid Eye Movement (REM) and nREM (N1, N2, N3) and wake
- Heart/pulse rate
- Snoring loudness
- Sleep/wake
- Head movement and position
- Snoring, sympathetic, behavioral and cortical arousals
- ECG,EOG, EMG waveform
- SpO_2
- Airflow
- Respiratory Effort
- Apneas and Hypopneas
- Oxygen desaturations.

The software identifies and rejects periods with poor electroencephalography signal quality. The full disclosure recording of derived signals and automated analyses can be visually inspected and edited prior to the results being integrated into a sleep study report.

Medical and history information can be input from a questionnaire. Responses are analyzed to provide a pre-test probability of Obstructive Sleep Apnea (OSA). The automated analyses of physiological data are integrated with the questionnaire data, medical and history information to provide a comprehensive report. Several report formats are available depending on whether the user has acquired more than one night of data, wishes to obtain a narrative summary report or provide patient reports.

The Sleep Profiler software can be used as a stand-alone application for use on Microsoft Windows 7 & 8 operating system platforms (desktop model). Alternatively, the user interface (i.e., entry or editing of information) can be delivered via a web-portal (portal model). The capability to enter or edit patient information, call the application to generate a study report, and/or download a report is provided using either the desktop PC application or web-portal application. The same analysis and report generation software is used for both the desktop and web-portal applications.

INTENDED USE:

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.

TECHNOLOGY:

The proposed Sleep Profiler has similar indications for use and uses the same fundamental technology as the legally marketed predicate devices to which substantial equivalency is claimed, the previously cleared version of the Sleep Profiler (K130007) and reference predicate device Apnea Risk Evaluation System (ARES), Model 610 (K112514) for the new indications and features that have been added to the software.

Specification	Sleep Profiler	Predicate Device, Sleep Profiler (K130007)	Reference Predicate Device, ARES Model 610 (K112514)
Classification	OLZ, Automated Event Detection Software for Polysomnograph with Electroencephalograph	OLZ, Automated Event Detection Software for Polysomnograph with Electroencephalograph	MNR, Ventilatory Effort Recorder

Advanced Brain Monitoring, Inc. Sleep Profiler

Specification	Sleep Profiler	Predicate Device, Sleep Profiler (K130007)	Reference Predicate Device, ARES Model 610 (K112514)
Indications for Use	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.	Sleep Profiler is intended for the diagnostic evaluation by a physician to assess sleep quality 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 and snoring.	The Apnea Risk Evaluation System (ARES) is indicated for use in the diagnostic evaluation by a physician of adult patients with possible sleep apnea. The ARES can record and score respiratory events during sleep (e.g., apneas, hypopneas, mixed apneas and flow limiting events). The device is designed for prescription use in home diagnosis of adults with possible sleep-related breathing disorders.
Intended Use	Analyze physiological data acquired during sleep.	Analyze physiological data acquired during sleep.	Analyze physiological data acquired during sleep.
Patient Population	Adults	Adults	Adults
Environment of Use	Physician office (data analysis and reporting) No limitation on where data are acquired.	Physician office (data analysis and reporting) No limitation on where data are acquired.	Physician office (data analysis and reporting) Home (data acquisition)

Advanced Brain Monitoring, Inc. Sleep Profiler

Specification	Sleep Profiler	Predicate Device, Sleep Profiler (K130007)	Reference Predicate Device, ARES Model 610 (K112514)
Derived Signals	• Sleep stages Rapid Eye Movement (REM) and nREM (N1, N2, N3) and wake • Heart/pulse rate • Snoring loudness • Sleep/wake • Head movement and position • Snoring, sympathetic, behavioral and cortical arousals • ECG,EOG, EMG waveform • SpO$_2$ • Airflow • Respiratory Effort • Apneas and Hypopneas • Oxygen desaturations	• Sleep stages Rapid Eye Movement (REM) and nREM (N1, N2, N3) and wake • Pulse rate • Snoring loudness • Sleep/wake • Head movement and position • Snoring, sympathetic, behavioral and cortical arousals • ECG,EOG, EMG waveform	• Sleep stages Rapid Eye Movement (REM) and nREM • Pulse rate • Snoring loudness • Sleep/wake • Head movement and position • Snoring, sympathetic, behavioral arousals • SpO$_2$ • Airflow • Respiratory Effort (Optional) • Apneas and Hypopneas • Oxygen desaturations
Signal quality	Auto-rejects bad signal quality in EEG with optional airflow and SpO2.	Auto-rejects bad signal quality in EEG.	Auto-rejects bad signal quality in EEG, airflow and SpO2
Sleep Measures	• Sleep, REM and N3 onset • Total sleep and recording times • Sleep efficiency • % time by sleep stage • Awakenings per hour • Wake after sleep onset	• Sleep, REM and N3 onset • Total sleep and recording times • Sleep efficiency • % time by sleep stage • Awakenings per hour • Wake after sleep onset	• Sleep onset • Total sleep and recording times • Sleep efficiency • % time by sleep stage
Sleep Staging	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)	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)	Based on one forehead EEG signal to differentiate REM and non-REM sleep, and behavioral measures from actigraphy, snoring and airflow to detect sleep from wake

Advanced Brain Monitoring, Inc. Sleep Profiler

Specification	Sleep Profiler	Predicate Device, Sleep Profiler (K130007)	Reference Predicate Device, ARES Model 610 (K112514)
Sleep Disordered Breathing (when respiratory signals are acquired)	• 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 SpO$_2$ 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)	None	• Detects apneas with airflow signal • Each apnea classified with the automated algorithms is labeled as an obstructive Apnea (Ap) or Apnea with arousal (ApA). • Detects hyponeas with airflow signal. Changes in SpO$_2$ are used to determine hypopnea severity • Hypopnea with arousals and a 4%, 3%, 1%, or 0% desaturation (H4A, H3A, H1A, H0A) • Hypopnea with no associated arousal (H4, H3, H1). • Hypopneas that do not meet the minimal 1% desaturation criteria must have at least one arousal indicator to be labeled.
Heart rate accuracy	20 to 250 bpm $\pm$ 5 bpm	20 to 250 bpm $\pm$ 5 bpm	20 to 250 bpm $\pm$ 5 bpm
Head Position	Via accelerometers Position accuracy 3º @ 30º C	Via accelerometers Position accuracy 3º @ 30º C	Via accelerometers Position accuracy 3º @ 30º C
Snoring Level	From microphone 40 dB @ 3% of dynamic range (min) 70 dB @ 90% of dynamic range (max) Accuracy 0.2 dB at mid range	From microphone 40 dB @ 3% of dynamic range (min) 70 dB @ 90% of dynamic range (max) Accuracy 0.2 dB at mid range	From microphone 40 dB @ 3% of dynamic range (min) 70 dB @ 90% of dynamic range (max) Accuracy 0.2 dB at mid range

Specification	Sleep Profiler	Predicate Device, Sleep Profiler (K130007)	Reference Predicate Device, ARES Model 610 (K112514)
User Editing	• Allows editing of sleep stage • Allows editing of auto-scored obstructive and quality events • User can insert missed events or convert obstructive to central	Allows editing of sleep stage	• Allows editing of sleep stage • Allows editing of auto-scored obstructive and quality events • User can insert missed events or convert obstructive to central
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 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. Optional: ○ AHI, numerical and graphical, supine and non-supine ○ RDI, numerical and graphical, supine and non-supine	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.	Graphic, narrative and patient Hx ○ Recording time ○ Sleep time ○ Valid sleep time ○ Sleep latency (Onset) ○ Sleep efficiency ○ AHI, numerical and graphical, supine and non-supine ○ RDI, numerical and graphical, supine and non-supine ○ #Apneas ○ #Hypopneas ○ Mean SpO2, %time < 90 %SpO2 ○ %time snoring > 30, 40, 50 and 60 dB ○ Pulse rate graph with autonomic activiations ○ Snoring level graph with snoring arousals ○ Head movement graph with behavioral arousals ○ Head position graph ○ Sleep vs. wake hypnogram ○ Physician interpretation and comments (free text) ○ Clinical History (narrative and tabular) ○ Sleep study findings ○ Treatment considerations

Specification	Sleep Profiler	Predicate Device, Sleep Profiler (K130007)	Reference Predicate Device, ARES Model 610 (K112514)
Reports, continued	o #Apneas o #Hypopneas o #RERAs o Mean SpO2, %time < 90 and < 88% SpO2		o Disease management considerations o Physician review and signature.
Two Night Reports	Multi-night and test-retest comparison table of statistics listed	Multi-night and test-retest comparison table of statistics listed	Multi-night and test-retest comparison table of statistics listed
Disease management comments	On report, drop down selection. o Cardiac Dysrhythmia o Restless Leg Syndrome o Sleep Disordered Breathing o Depression	On report, drop down selection. o Cardiac Dysrhythmia o Restless Leg Syndrome o Sleep Disordered Breathing o Depression	On report, drop down selection. o Cardiac Dysrhythmia o Restless Leg Syndrome o Central sleep apnea Plus automatically generated requiring confirmation or editing from user. o Numerous messages related to sleep apnea.
Compatibility	Sleep Profiler will operate on any personal computer with Windows XP operating system and at least 2 GB of RAM. The speed by which a study will process is dependent on the computer processer and the amount of RAM.	Sleep Profiler will operate on any personal computer with Windows XP operating system and at least 2 GB of RAM. The speed by which a study will process is dependent on the computer processer and the amount of RAM.	Personal computer with Pentium 4, 1 GB RAM or higher processor (or equivalent with Windows XP or 7 Operating System
Web interface computer requirements	• 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	• 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, Firefox or Chrome, Opera	• Processor : Minimum 2.8 GHz • Operating System: Windows XP or 7 • JAVA version 6 or greater • RAM: 1GB • USB port: 1 • 6. Internet connection: constant • Web browser: Internet Explorer, Firefox or Chrome

Specification	Sleep Profiler	Predicate Device, Sleep Profiler (K130007)	Reference Predicate Device, ARES Model 610 (K112514)
Web interface server requirements.	**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	**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	**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
Computer/portal Security	• The person installing the Java applet must have administrator privileges. • User must have rights to the account and group to access data via the portal. • The firewall is not configured to prevent input or output communication with access to the server via ports 22 and 30-39.	• The person installing the Java applet must have administrator privileges. • User must have rights to the account and group to access data via the portal. • The firewall is not configured to prevent input or output communication with access to the server via ports 22 and 30-39.	• The person installing the Java applet must have administrator privileges. • User must have rights to the account and group to access data via the portal. • The firewall is not configured to prevent input or output communication with access to the server via ports 22 and 30-39.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

SUMMARY OF NON-CLINICAL TESTS:

Support for the substantial equivalence of the Sleep Profiler was provided as a result of risk management and software testing. Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

The Sleep Profiler software has been thoroughly tested through verification of specifications and system level validation. The results of the verification and validation activities that have been performed demonstrate that the software meets requirements for safety, function, and intended use.

SUMMARY OF CLINICAL TESTS:

The Sleep Profiler software accuracy was clinically validated with signals acquired with the X8 System concurrent to polysomnography (PSG). The following endpoints were evaluated and met:

Endpoint	The accuracy of the Sleep Profiler-PSG2 software will be equivalent to the predicate device(s):
1	when applied to signals obtained with the FleX8 and compared to PSG to stage sleep.
2	when applied to signals obtained with the FleX8 and PSG, and compared to PSG for detection of sleep disordered breathing for use in diagnosing OSA based on a minimum targeted positive likelihood ratios for an AHI > 5 and 15 are 3.5 and 5.0 respectively.

Where, AHI is the Apnea-Hypopnea Index. The AHI is the number of apnea and hypopnea events per hour of sleep.

The results compared auto-detected staging and sleep disordered breathing (i.e., apnea-hypopnea index) to PSG results obtained by one rater per study. The results confirm Sleep Profiler's positive likelihood ratio for overall AHI vs. PSG is equivalent to the predicate ARES. The Sleep Profiler achieves a positive likelihood ratio for REM AHI vs. PSG REM AHI equivalent to the ARES positive likelihood ratio across all sleep stages.

	ARES		Sleep Profiler Overall		Sleep Profiler REM	
	AHI ≥ 5	AHI ≥ 15	AHI ≥ 5	AHI ≥ 15	AHI ≥ 5	AHI ≥ 15
Sample size (n)	73	73	60	60	40	40
Sensitivity	0.98	0.92	1.00	1.00	0.84	0.73
Specificity	0.76	0.91	0.85	0.97	0.90	0.96
Likelihood ratio+	4.08	10.22	6.67	33.0	8.84	18.33
Likelihood ratio-	0.03	0.09	0.00	0.00	0.17	0.28

Where likelihood ratio + is the likelihood ratio of a positive test and likelihood ratio – is the likelihood ratio of negative test. The likelihood ratio + is the ratio of the false negative rate (1-sensitivity) and true negative rate (specificity); calculated as (1-sensitivity)/specificity. The likelihood ratio – is the ratio of the true positive rate (sensitivity) and false positive rate (1-specificity); calculated as sensitivity/(1-specificity)

Additionally the Sleep Profiler staging algorithms were compared in a sub-set of subjects (n=43) with at least 4 hours of X8 diagnostic recording time. The results for the weighted majority agreement of three raters are presented in the cross-tabulation below:

		Epochs assigned by Sleep Profiler						% agreement	
	Overall	Wake	N1	N2	N3	REM	Total	Positive	Negative
Epochs	Wake	5449	950	567	45	413	7424	0.73	0.94
assigned	N1	564	431	600	44	113	1752	0.25	0.93
by	N2	582	801	9673	1408	118	12582	0.77	0.84
Expert	N3	34	19	1035	3591	25	4704	0.76	0.94
Scoring	REM	194	221	550	1	2783	3749	0.74	0.97
	No-Cons	378	220	325	46	181	1150		
	Total	7201	2642	12750	5135	3633	31361		

The results from the previously cleared application of the Sleep Profiler auto-staging software to signals frontal PSG leads is presented below.

		Epochs assigned by Predicate Sleep Profiler						% agreement	
	Overall	Wake	N1	N2	N3	REM	Total	Positive	Negative
Epochs	Wake	6730	921	557	27	296	8531	0.79	0.95
assigned	N1	807	1962	1652	40	493	4954	0.40	0.91
by	N2	348	1426	11848	958	218	14798	0.80	0.83
Expert	N3	36	24	1194	3928	8	5190	0.76	0.97
Scoring	REM	178	530	681	35	3641	5065	0.72	0.97
	No-Cons	124	91	324	67	47	653		
	Total	8223	4954	16256	5055	4703	39191		

Differences between the two studies are the result of inter-rater variability in the application of the American Academy of Sleep Medicine scoring rules to wake and stage N1 resulting from sleep disordered breathing are explained with supplemental analyses. A new software feature marks epochs that may benefit from manual review to improve the accuracy of the staging during manual review.

CONCLUSION:

Advanced Brain Monitoring considers the Sleep Profiler to be substantially equivalent to the predicate devices.