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

February 18, 2015

Neurotronics, Inc.
David Pezet
Quality Manager
3600 NW 43rd Street, Suite F1
Gainesville, FL 32606

Re: K142774
Trade/Device Name: Polysmith Sleep System NTI6600
Regulatory Class: II
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Product Code: OLZ, OLV, DQA
Dated: January 12, 2015
Received: January 13, 2015

Dear Mr. Pezet:

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" (21CFR 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,

Felipe Aguel -S

for Carlos L. Peña, Ph.D., M.S.
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 on last page.

510(k) Number *(if known)*

K142774

Device Name
Polysmith Sleep System, Model NTI6600

Indications for Use *(Describe)*

The device is intended to measure, amplify, and record physiological signals acquired from a patient for archival in a sleep study. The physiological signals are recorded and conditioned for analysis and display. The data may be analyzed in real-time or offline on dedicated polysomnography software running on a personal computer by a qualified sleep clinician to aid in the diagnosis of Sleep Disorders.

The device is intended for use by healthcare professionals within a hospital, laboratory, clinic, or nursing home; or outside of a medical facility under direct supervision of a medical professional.

The device is intended for use on both adults and children only under the direction of a physician or qualified sleep technician.

The device or any accessory, does not include alarms, and is not intended to be used as a critical component of an alarm system.

The device or any accessory, is not to be used alone as an apnea monitor or as a component in an apnea monitoring system.

The device or any accessory, is not to be used alone as a life support device or as a critical component of a life support system.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

SUMMARY DATE:

February 18, 2015

510K SUBMITTER:

Neurotronics, Inc.
3600 NW 43rd Street, Suite FL
Gainesville, FL, 32606

Phone: 352.372.9955
Fax: 815.550.2871

Primary Contact:

Name: David Pezet
Email: quality@neurotronics.com

Title: Quality Manager
Phone: 352.372.9955 Ext 355

Establishment Registration Number:

1063925

DEVICE TYPE (COMMON NAME):

Polysomnography Monitoring System

PROPRIETARY NAME OF THE DEVICE:

Polysmith Sleep System, Model NTI6600

CLASSIFICATION:

Product Code:

Product Code	Device	Regulation Description	Regulation Number
OLZ	Automatic Event Detection Software For Polysomnograph With Electroencephalograph	Electroencephalograph.	882.1400

Subsequent Product Code:

Product Code	Device	Regulation Description	Regulation Number
OLV	Standard Polysomnograph With Electroencephalograph	Electroencephalograph.	882.1400
DQA	Oximeter	Oximeter.	870.2700

PREDICATE DEVICES

Submitter/Holder	Device Name	Model	Product Codes	510(K)
Neurotronics, Inc.	Polysmith Sleep System	NTI5498	OLZ, DQA, OLV	K062943
Nihon Kohden Corp.	PSG-1100 Sleep Diagnostic System	PSG-1100	GWQ, OLV	K120888

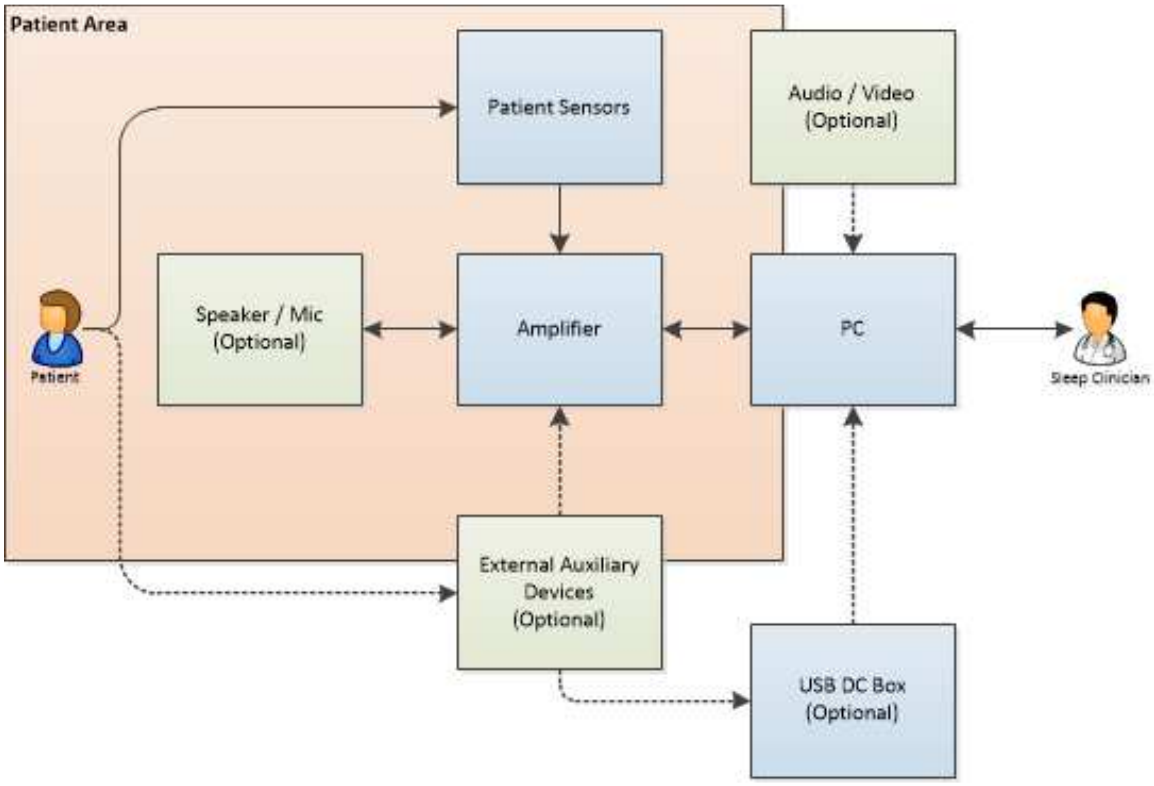
DESCRIPTION

The Polysmith Sleep System, Model NTI6600 is intended to amplify and record physiologic potentials used for Polysomnography (PSG) or Sleep Studies. The device consists of a compatible amplifier, head box, PC, patient sensors, and may include optional external devices, USB DC Box, and audio/video input devices.

Compatible amplifiers may use commercially available sensors and electrodes, an internal SpO2 module, and internal pressure transducers to collect, digitize, and send physiological signals to the host PC.

The Polysmith software may record from video, speaker and microphone equipment. The Polysmith software may also record auxiliary signals from compatible amplifiers or USB DC Box which allow for data inputs from compatible sources.

Polysmith records and displays the data for online or offline review. Qualified practitioners use the information to score Polysomnograms and diagnose Sleep Disorders.



1 Polysmith Sleep System Basic Block Diagram

INTENDED USE

The device is intended to measure, amplify, and record physiological signals acquired from a patient for archival in a sleep study. The physiological signals are recorded and conditioned for analysis and display. The data may be analyzed in real-time or offline on dedicated polysomnography software running on a personal computer by a qualified sleep clinician to aid in the diagnosis of sleep disorders.

The device is intended for use by healthcare professionals within a hospital, laboratory, clinic, or nursing home; or outside of a medical facility under direct supervision of a medical professional.

The device is intended for use on both adults and children only under the direction of a physician or qualified sleep technician.

The device, or any accessory, does not include alarms, and is not intended to be used as a critical component of an alarm system.

The device, or any accessory, is not to be used alone as an apnea monitor or as a component in an apnea monitoring system.

The device, or any accessory, is not to be used alone as a life support device or as a critical component of a life support system.

PREDICATE COMPARISON

Intended Use Comparison

The Polysmith Sleep System, Model NTI6600 improves upon the predicates' current capabilities access and review of on-line or previously recorded acquisitions. These improvements do not change the indications for use for the devices which it is an accessory. This device is intended to aid in diagnosis of sleep disorders, and other related disorders.

Technical Comparison

The Polysmith Sleep System, Model NTI6600 includes and improves upon the same feature set as found in the predicates. Therefore Neurotronics believes the Polysmith Sleep System, Model NTI6600 is substantially equivalent to the Polysmith Sleep System, Model NTI5498 (K062943), and PSG-1100 Sleep Diagnostic System (K120888).

Software Technical Comparison

Software Technical Comparison	**Polysmith Sleep System, NTI6600 Polysmith (NEW)**	**Polysmith Sleep System, NTI5498 Polysmith (K062943)**	**PSG-1100 (K120888)**
Display electrical activity of the brain and other physiological signals on a monitor	Yes	Yes	Yes
Device uses Windows on a 32-bit or 64-bit computer	32-bit & 64-bit	32-bit	32-bit & 64-bit
Display waveforms in acquisition and review	Yes	Yes	Yes
Maximum number of waveforms on screen	32	32	32
Simultaneously view waveforms from multiple EEG/PSG instruments and display values from external instruments	On-line & Off-line	On-line & Off-line	On-line & Off-line
Variable waveform display duration	On-line & Off-line	On-line & Off-line	On-line & Off-line
Change waveform parameters (pattern, montage, amplifier conditions, AV induction)	On-line & Off-line	On-line & Off-line	On-line & Off-line
The device can record and measure vital signs (including ECG, EMG,	On-line & Off-line	On-line & Off-line	On-line & Off-line

Software Technical Comparison	Polysmith Sleep System, NTI6600 Polysmith (NEW)	Polysmith Sleep System, NTI5498 Polysmith (K062943)	PSG-1100 (K120888)
Respiration, Ocular Motility, SpO2, and CO2)			
Nihon Kohden Amplifiers Compatibility	Yes	Yes	Yes
Lifelines Trackit Series Amplifiers Compatibility	Yes	Yes	Yes
USB DC Box Compatibility	Yes	Yes	Yes
Sleep Stage Analysis	On-line & Off-line	On-line & Off-line	On-line & Off-line
Arrhythmia Analysis	Off-line (integrated K012686)	Off-line (integrated K012686)	Off-line (integrated K012686)
Respiratory Event Analysis	On-line & Off-line	On-line & Off-line	On-line & Off-line
SpO2 Desaturation Analysis	On-line & Off-line	On-line & Off-line	On-line & Off-line
Limb Movement Event Analysis	On-line & Off-line	On-line & Off-line	On-line & Off-line
Snore Event Analysis	On-line & Off-line	On-line & Off-line	On-line & Off-line
FFT Analysis	Off-line	Off-line	Off-line
Manual Event Scoring	On-line & Off-line	On-line & Off-line	On-line & Off-line
Manual Custom Event Scoring	On-line & Off-line	On-line & Off-line	On-line & Off-line
Trend Plots	On-line & Off-line	On-line & Off-line	On-line & Off-line
Display patient video along with waveforms	On-line & Off-line	On-line & Off-line	On-line & Off-line
Record Patient Audio and Video	Yes	Yes	Yes
Integrated Intercom Interface	Yes (with PMU710)	No	No
For use by medical personnel in a medical facility, physician's office, laboratory, clinic, or nursing home	Yes	Yes	Yes

Software Technical Comparison	Polysmith Sleep System, NTI6600 Polysmith (NEW)	Polysmith Sleep System, NTI5498 Polysmith (K062943)	PSG-1100 (K120888)
Any patient population including adults and children as determined by a trained professional	Yes	Yes	Yes
Patient Database and Scheduling	Yes	Yes	Yes
Reporting and Custom Report Capabilities	Yes	Yes	Yes
HL7 Interface Capabilities	Yes	Yes	Yes
Remote Access Capabilities	On-line & Off-line	On-line & Off-line	On-line & Off-line
Display Resolution	>=1600 x 1200	>=1600 x 1200	>=1600 x 1200
File Format	XDF (XML), EDF	XDF (XML), EDF	XDF (XML), EDF
File Management	Yes	Yes	Yes
Compatible Amplifiers for Recording	• Neurotronics Sphinx PMU710 (NEW) • Neurotronics Sphinx PMU700 (K062943) • Neurotronics Nomad PMU800 (K092699) • Nihon Kohden PSG-1100 (K120888) • Nihon Kohden EEG-1200a Amplifiers (K113117, K080546) • Nihon Kohden Wireless Input Unit, Model WEE-1000a	• Neurotronics Sphinx PMU700 (K062943) • Nihon Kohden Wireless Input Unit, Model WEE-1000a Series (K033475) • Nihon Kohden Electrode Junction Box, Model JE-921a (K050833) • Nihon Kohden PSG Input Box, Model JE-912ak (K022121) • Nihon Kohden Neurofax, Models EEG-1100a, EEG-9100a	• Neurotronics Sphinx PMU700 (K062943) • Neurotronics Nomad PMU800 (K092699) • Nihon Kohden PSG-1100 (K120888) • Nihon Kohden EEG-1200a Amplifiers (K113117, K080546) • Nihon Kohden Wireless Input Unit, Model WEE-1000a Series (K033475) • Nihon Kohden Electrode Junction Box,

Software Technical Comparison	Polysmith Sleep System, NTI6600 Polysmith (NEW)	Polysmith Sleep System, NTI5498 Polysmith (K062943)	PSG-1100 (K120888)
	Series (K033475) • Nihon Kohden Electrode Junction Box, Model JE-921a (K050833) • Nihon Kohden PSG Input Box, Model JE-912ak (K022121) • Nihon Kohden Neurofax, Models EEG-1100a, EEG-9100a (K011204, K992742) • Lifelines Trackit Series amplifiers (K010460)	(K011204, K992742) • Lifelines Trackit Series amplifiers (K010460)	Model JE-921a (K050833) • Nihon Kohden PSG Input Box, Model JE-912ak (K022121) • Nihon Kohden Neurofax, Models EEG-1100a, EEG-9100a (K011204, K992742) • Lifelines Trackit Series amplifiers (K010460)

Amplifier Technical Comparison

Amplifier Technical Comparison	Polysmith Sleep System, NTI6600 Sphinx PMU710 (NEW)	Polysmith Sleep System, NTI5498 Sphinx PMU700 (K062943)	PSG-1100 (K120888)
Number of Channels	23	33	42
Pulse Oximeter	Integrated Nihon Kohden Oximeter Module	Integrated Nonin Oximeter Module	Integrated Nihon Kohden Oximeter Module
Input Impedance	>= 10 M Ohm	>= 10 M Ohm	100 M ohm
Calibration Check	Step square 50uV	Step square 50uV	Step square 50uV
Impedance Check	Yes	Yes	Yes
Common-Mode Rejection Ratio (CMRR)	>= 90 dB	>= 90 dB	>= 105 dB
Noise Level	< 2 µV p-p (0.1 to 60 Hz)	< 2 µV p-p (0.53 to 60 Hz)	< 1.5 uV p-p (0.53 to 60Hz)
Hardware Frequency Response	.072 Hz to 300 Hz	0.1 Hz to 100 Hz	0.08 to 300 Hz
Software High-pass Filter	.072 Hz DC Standard	.1 Hz DC Standard	0.08 to 53 Hz DC Standard
Software Low-pass Filter	15 Hz to 300 Hz	15 Hz to 100 Hz	15 to 300 Hz
AC Filter	50 or 60 Hz	50 or 60 Hz	50 or 60 Hz
Sensitivity	Off, 0.1 to 200 uV/mm (20 steps) DC: Off, 10 to 200 mV/mm (10 steps)	Off, 0.1 to 200 uV/mm (20 steps) DC: Off, 10 to 200 mV/mm (10 steps)	Off, 0.1 to 200 uV/mm (20 steps) DC: Off, 10 to 200 mV/mm (10 steps)
A-D Conversion	16 bits	16 bits	16 bits
Sampling	1000 Hz	1000 Hz	All Channels 200, 250, 500, 1000, 2000 Hz
Power	Mains	USB	100-240 V +/- 10% 50 / 60 Hz 42 VA (Main Unit only)
PC Connection	Ethernet	USB	Ethernet
Operating Environment Temperature	10 to 35 C	0°C to +50°C	10 to 35 degree Celsius
Operating Environment Humidity	0 to 93% non-condensing	10% to 90% non-condensing	30 to 80% Humidity
Any patient population including adults and children as determined by a trained professional	Yes	Yes	Yes

Performance Data

Applied Standards

Standards Number	Standards Organization	Standards Title
62304	AAMI ANSI IEC	Medical device software - Software life cycle processes
14971	AAMI ANSI ISO	Medical devices - Applications of risk management to medical devices
62366	AAMI ANSI IEC	Medical devices - Application of usability engineering to medical devices
60601-1	AAMI ANSI IEC	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
60601-1-2	AAMI ANSI IEC	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3)
60601-2-26	IEC	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs

Clinical Data Summary

Automated Analysis

Methodology

Our data included analysis of 8,053 recorded epochs, of which 7,606 were scored. These studies were chosen at random from existing sleep studies of acceptable signal quality from accredited labs.

The human scoring was completed by two expert scorers from different organizations. Each expert is a registered sleep clinician with at least 5 years' experience scoring sleep records.

The studies used for this testing were not used to train the algorithm. The experts were not affiliated with the development of the algorithm. Furthermore, these studies were chosen at random from a sleep lab independent of Neurotronics.

Scorers were instructed to make a copy of the ten test records to a separate folder before testing. This is to ensure the file settings do not change between test runs. Scorers were instructed to score the studies using the default Polysmith scoring settings using AASM scoring rules. Scorers were instructed to not change any file settings including the montage.

Results

Consistent with the AASM Inter-Scorer Reliability program, the percentage of agreement is calculated by True Positives (Agreements) divided by the total number of epochs compared. The overall results are as follows,

	Average Human Scoring Agreement	Average Automated Analysis Agreement	Confidence Interval +/- (95.0%)
Sleep Staging	82.8%	71.53%	3.04%
Microarousal	88.8%	80.15%	3.98%
Apnea	98.7%	97.28%	1.32%
Hypopnea	96.4%	95.44%	2.55%
Desaturation	97.1%	95.72%	1.32%
Limb Movement	98.9%	92.57%	4.35%

Gender	
Male	10
Female	0
Total	**10**

BMI	
Min	22.50
Max	42.60
Avg	31.81

Age	
Min	16.0
Max	74.3
Avg	52.3

AHI	
Min	19.3
Max	69.8
Avg	41.0

Additional Sleep Staging Analysis

Methodology

Additionally, twenty sleep studies were procured from at least three different sources. Each study was manually scored by three independent scorers. Each scorer was a registered sleep specialist with at least five years' experience in the field. Each scorer has had some prior experience using Polysmith to manually score studies. The manual scoring was compared against the automated scoring to determine the accuracy of the analysis algorithm.

Each scorer was given a collection of files that contain the 20 studies along with a copy of Polysmith. This copy of Polysmith had the capability to score but did not have any automated analysis capability. Each scorer was instructed to manually score each study for sleep stage, arousal, desaturation, and airflow events including apnea, and hypopnea, and to only use the copy of Polysmith provided. The studies were scored blind to all other scorers including the Polysmith automated scoring. Scorers were instructed to only follow AASM guidelines for scoring all events. All files were configured with a minimal montage. Scorers were instructed to, as much as possible, use this montage without alteration.

Scorers were instructed that some files are split-night studies. For these studies, scorers were instructed to use the CPAP Flow channel for scoring Hypopnea and Flow Limitation after CPAP start.

Once the files were manually scored, they were returned to Neurotronics for evaluation. Each file was then scored by the automated analysis and compared to the three human scorers.

Each of the three scorer files were compared against each other to determine the true sleep staging (consensus). These results use the majority method of comparison (2/3 majority-rule). Epochs for which there was no agreement among the human scorers were discarded (non-consensus).

Results

The results from this collection of studies are as follows,

Polysmith Scoring Agreement								
-	W	N1	N2	N3	R	Totals	Positive	Negative
W	**2907**	859	279	44	202	**4291**	67.75%	92.12%
N1	378	**745**	777	24	117	**2041**	36.50%	92.62%
N2	336	367	**6606**	895	90	**8294**	79.65%	90.39%
N3	4	6	51	**757**	1	**819**	92.43%	99.65%
R	136	305	333	2	**1335**	**2111**	63.24%	95.58%
Totals	**3761**	**2282**	**8046**	**1722**	**1745**	**17556**	-	-

Total Agreement	k Lower Bound	kappa	k Upper Bound
70.35%	0.57	0.58	0.59

Total Epochs	Total Consensus Epochs	Total Non-Consensus Epochs
18657	17556	1101

Gender	
Male	14
Female	6
Total	**20**

BMI	
Min	23.30
Max	56.00
Avg	34.66

Age	
Min	16.0
Max	74.3
Avg	52.3

CONCLUSION

Based on the results of the Intended Use Comparison, the Technical Comparison, and Testing Data, it is believed that the Polysmith Sleep System, Model NTI6600 presents no new questions of safety and effectiveness, and is substantially equivalent to the features provided by the identified predicates.