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

January 19, 2017

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

Re: K161650
Trade/Device Name: Polysmith Sleep System, Model NTI7593
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLV, DQA, MLO, OLZ
Dated: December 20, 2016
Received: December 21, 2016

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" (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 -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161650

Device Name
Polysmith Sleep System, Model NTI7593

Indications for Use *(Describe)*

The Polysmith Sleep System, Model NTI7593 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 Polysmith Sleep System, Model NTI7593 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 Polysmith Sleep System, Model NTI7593 is intended for use on both adults and children only under the direction of a physician or qualified sleep technician.

The Polysmith Sleep System, Model NTI7593 includes automatic detection of some arrhythmias (including some potentially life threatening arrhythmias), however detection of an arrhythmia may be performed with 30 seconds or more delay, and is based on a single ECG lead only.

The Polysmith Sleep System, Model NTI7593, or any accessory, is not intended for the life monitoring of high risk patients, does not include or trigger alarms, and is not intended to be used alone as, or a critical component of,

- an alarm or alarm system;
- an apnea monitor or apnea monitoring system; or
- a life monitor or life monitoring 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K161650 510(k) Summary

Summary Date:
January 19, 2017

510(k) Submitter:

Neurotronics, Inc.
3600 NW 43rd Street, Suite F1
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

Common Name:
Polysomnography Monitoring System

Trade Name:
Polysmith Sleep System, Model NTI7593

510(k) Review Panel:
Neurology

Classification:

PRIMARY PRODUCT CODE

Product Code	Device	Regulation Description	Regulation Number
OLV	Standard Polysomnograph With Electroencephalograph	Electroencephalograph	882.1400

Subsequent Product Codes:

Product Code	Device	Regulation Description	Regulation Number
OLZ	Automatic Event Detection Software For Polysomnograph With Electroencephalograph	Electroencephalograph	882.1400
DQA	Oximeter	Oximeter	870.2700
MLO	Electrocardiograph, Ambulatory, With Analysis Algorithm	Medical magnetic tape recorder	870.2800

PREDICATE DEVICE

Submitter/Holder	Device Name	Model	Product Codes	510(K) Number
Neurotronics, Inc.	Polysmith Sleep System	NTI6600	OLV, DQA, OLZ	K142774

REFERENCE DEVICE

Submitter/Holder	Device Name	Model	Product Code	510(K) Number
Nihon Kohden Corp.	Nihon Kohden Bedside Monitor	BSM 9100A Series	MHX	K082785

Device Description

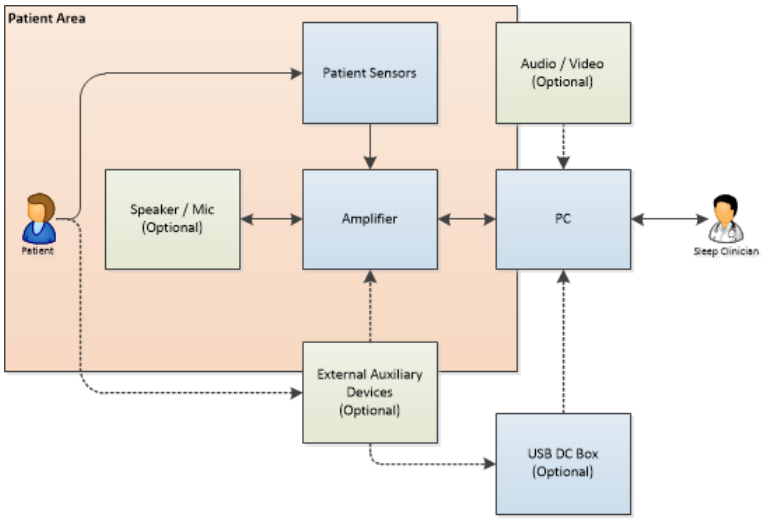
The following description of The Polysmith Sleep System, Model NTI7593 remains unchanged from the previous model Polysmith Sleep System, Model NTI6600.

The Polysmith Sleep System, Model NTI7593 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.



Polysmith Sleep System Basic Block Diagram

Intended Use

The Polysmith Sleep System, Model NTI7593 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 Polysmith Sleep System, Model NTI7593 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 Polysmith Sleep System, Model NTI7593 is intended for use on both adults and children only under the direction of a physician or qualified sleep technician.

The Polysmith Sleep System, Model NTI7593 includes automatic detection of some arrhythmias (including some potentially life threatening arrhythmias), however detection of an arrhythmia may be performed with 30 seconds or more delay, and is based on a single ECG lead only.

The Polysmith Sleep System, Model NTI7593, or any accessory, is not intended for the life monitoring of high risk patients, does not include or trigger alarms, and is not intended to be used alone as, or a critical component of,

- an alarm or alarm system;
- an apnea monitor or apnea monitoring system; or
- life monitor or life monitoring system.

Predicate Comparison

INTENDED USE COMPARISON

The Polysmith Sleep System, Model NTI7593 improves upon the original model's current capabilities of data analysis for arrhythmia related events. These improvements do not change the indications for use for the devices which it is an accessory. This device continues to be intended to aid in diagnosis of sleep disorders, and other related disorders, as arrhythmia events are identified as related disorders by the American Academy of Sleep Medicine. The change clarifies the functionality of the arrhythmia detection feature and that the feature is not intended for life monitoring of high-risk patients.

Polysmith Sleep System, NTI7593 (NEW)	Polysmith Sleep System, NTI6600 (K142774)
The Polysmith Sleep System, Model NTI7593 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 Polysmith Sleep System, Model NTI7593 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 Polysmith Sleep System, Model NTI7593 is intended for use on both adults and children only under the direction of a physician or qualified sleep technician. The Polysmith Sleep System, Model NTI7593 includes automatic detection of some arrhythmias (including some potentially life threatening arrhythmias), however detection of an arrhythmia may be performed with 30 seconds or more delay, and is based on a single ECG lead only. The Polysmith Sleep System, Model NTI7593, or any accessory, is not intended for the life monitoring of high risk patients, does not include or trigger alarms, and is not intended to be used alone as, or a critical component of, • an alarm or alarm system; • an apnea monitor or apnea monitoring system; or • life monitor or life monitoring system.	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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATES

The Polysmith Sleep System, Model NTI7593 includes and improves upon the same feature set as found in the predicate software. Therefore, Neurotronics believes the Polysmith Sleep System, Model NTI7593 is substantially equivalent to the Polysmith Sleep System, Model NTI6600 (K142774), and the arrhythmia analysis performance of the reference device, BSM 9100A Series Nihon Kohden Bedside Monitor (K082785).

Software Technical Comparison

Software Technical Comparison	Polysmith Sleep System, NTI7593 Polysmith (NEW)	Polysmith Sleep System, NTI6600 Polysmith (K142774)
Display electrical activity of the brain and other physiological signals on a monitor	Yes	Yes
Device uses Windows on a 32-bit or 64-bit computer	32-bit & 64-bit	32-bit & 64-bit
Display waveforms in acquisition and review	Yes	Yes
Maximum number of waveforms on screen	32	32
Simultaneously view waveforms from multiple EEG/PSG instruments and display values from external instruments	On-line & Off-line	On-line & Off-line
Variable waveform display duration	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
The device can record and measure vital signs (including ECG, EMG, Respiration, Ocular Motility, SpO2, and CO2)	On-line & Off-line	On-line & Off-line
Nihon Kohden Amplifiers Compatibility	Yes	Yes
Lifelines Trackit Series Amplifiers Compatibility	Yes	Yes
USB DC Box Compatibility	Yes	Yes
Sleep Stage Analysis	On-line & Off-line	On-line & Off-line
Arrhythmia Analysis	On-line & Off-line	Off-line (integrated K012686)
Respiratory Event Analysis	On-line & Off-line	On-line & Off-line
SpO2 Desaturation Analysis	On-line & Off-line	On-line & Off-line
Limb Movement Event Analysis	On-line & Off-line	On-line & Off-line
Snore Event Analysis	On-line & Off-line	On-line & Off-line
FFT Analysis	Off-line	Off-line
Manual Event Scoring	On-line & Off-line	On-line & Off-line
Manual Custom Event Scoring	On-line & Off-line	On-line & Off-line
Trend Plots	On-line & Off-line	On-line & Off-line
Display patient video along with waveforms	On-line & Off-line	On-line & Off-line
Record Patient Audio and Video	Yes	Yes

Software Technical Comparison	Polysmith Sleep System, NTI7593 Polysmith (NEW)	Polysmith Sleep System, NTI6600 Polysmith (K142774)
Integrated Intercom Interface	Yes (with PMU710)	Yes (with PMU710)
For use by medical personnel in a medical facility, physician's office, laboratory, clinic, or nursing home	Yes	Yes
Any patient population including adults and children as determined by a trained professional	Yes	Yes
Patient Database and Scheduling	Yes	Yes
Reporting and Custom Report Capabilities	Yes	Yes
HL7 Interface Capabilities	Yes	Yes
Remote Access Capabilities	On-line & Off-line	On-line & Off-line
Display Resolution	>=1600 x 1200	>=1600 x 1200
File Format	XDF (XML), EDF	XDF (XML), EDF
File Management	Yes	Yes

Software Technical Comparison	Polysmith Sleep System, NTI7593 Polysmith (NEW)	Polysmith Sleep System, NTI6600 Polysmith (K142774)
Compatible Amplifiers for Recording	• Neurotronics Sphinx PMU710 (K142774) • 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, 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)	• Neurotronics Sphinx PMU710 (K142774) • 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, 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)

Arrhythmia Analysis Event Comparison

Events detected by the third-party holter analysis software used with Polysmith Sleep System model NTI6600 compared to the integrated algorithm used in the new Polysmith software in model NTI7593. The newly integrated algorithm is the same algorithm implemented in the reference device, BSM-9100A (K082785) for applicable event types. This software allows the subject device to perform real-time arrhythmia analysis (with a 30 second or more delay for the applicable event types listed below).

Analysis Events	Polysmith Sleep System, NTI6600 (K142774)	Polysmith Sleep System, NTI7593 (NEW)	Nihon Kohden Bedside Monitor BSM-9100A (K082785)
Pause	Yes	**Yes**	Yes
Sinus Tachycardia	Yes	**Yes**	Yes
Extreme Tachycardia	No	No	Yes
Bradycardia	Yes	**Yes**	Yes
Extreme Bradycardia	No	No	Yes
Wide-Complex Tachycardia (Ventricular tachycardia)	Yes	**Yes**	Yes
Narrow-Complex Tachycardia (Supraventricular tachycardia)	Yes	**Yes**	Yes
Atrial Fibrillation (Irregular R-R)	No	**Yes**	Yes
Asystole	Yes	**Yes**	Yes
PVC	Yes	**Yes**	Yes
Early PVC	Yes	**Yes**	Yes
PVC Run	No	No	Yes
Frequent PVC	No	No	Yes
Multiform PVC	No	No	Yes
Idioventricular Rhythm (Ventricular Bradycardia)	No	**Yes**	Yes
Accelerated Idioventricular Rhythm (Ventricular Rhythm)	No	**Yes**	Yes
Bigeminy	Yes	**Yes**	Yes
Trigeminy	No	**Yes**	Yes
Couplet	Yes	**Yes**	Yes
Ventricular Fibrillation	No	**Yes**	Yes

Analysis Events	Polysmith Sleep System, NTI6600 (K142774)	Polysmith Sleep System, NTI7593 (NEW)	Nihon Kohden Bedside Monitor BSM-9100A (K082785)
Prolonged R-R	No	No	Yes
No Pacer Pulse	No	No	Yes
Pacer Non-Capture	No	No	Yes
ST Level	Yes	No	Yes
SupraVentricular Ectopic (SVE)	Yes	No	No

Non-Clinical Performance Data

Applied Standards

The following applied standards are related to the integration of the arrhythmia analysis algorithm within the Polysmith software. All other applied standards from the previously registered Polysmith Sleep System, Model NTI6600 (K142774) remain unchanged.

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
EC57	AAMI ANSI	Testing And Reporting Performance Results of Cardiac Rhythm And St-Segment Measurement Algorithms.

Performance Results

Arrhythmia Analysis verification was performed in a manner consistent with the applicable portions of the AAMI ANSI EC57:2012, Testing and Reporting Performance Results of Cardiac Rhythm and St-Segment Measurement Algorithms standard.

The arrhythmia analysis results are to be reviewed by a qualified clinician and are not to serve as results for direct diagnosis or treatment of arrhythmia conditions. The arrhythmia analysis function is only to provide indicators for further investigation.

QRS & VPC Detection Performance

		Polysmith Sleep System, NTI7593 (NEW)		
		MIT	**AHA**	**NST**
QRS	**Se**	99.56%	99.56%	98.10%
	+P	99.67%	99.80%	84.78%
Ventricular Ectopic Beat	**Se**	91.85%	85.46%	88.28%
	+P	96.94%	98.18%	90.94%
	FPR	0.220%	0.163%	0.881%

MIT: The Massachusetts Institute of Technology–Beth Israel Hospital Arrhythmia Database
AHA: The American Heart Association Database for Evaluation of Ventricular Arrhythmia Detectors
NST: The Noise Stress Test Database
+P: Predictivity
Se: Sensitivity
FPR: False Positive Rate

Arrhythmia Detection Statistical Summary

		Polysmith Sleep System, NTI7593 (NEW)
Bigeminy	**E Se**	90%
	E +P	91%
Trigeminy	**E Se**	87%
	E +P	64%
R-on-T	**Se**	68.17%
	+P	65.54%
	FPR	0.267%
Asystole	**E Se**	100%

		Polysmith Sleep System, NTI7593 (NEW)
	E +P	100%
Idioventricular Rhythm	**E Se**	50%
	E +P	100%
Accelerated Idioventricular Rhythm	**E Se**	62%
	E +P	57%
Ventricular Fibrillation	**E Se**	94%
	E +P	88%
	D Se	83%
	D +P	94%
Ventricular Tachycardia	**E Se**	100%
	E +P	86%
Supraventricular Tachycardia	**E Se**	77%
	E +P	18%
Pause	**E Se**	100%
	E +P	92%
Couplet	**E Se**	83%
	E +P	96%
	Avg E Se	62.00%
	Avg E +P	70.00%
Atrial Fibrillation	**E Se**	91%

		Polysmith Sleep System, NTI7593 (NEW)
	E +P	47%
	D Se	75%
	D +P	57%
	NST E Se	-
	NST E +P	0%
	NST D Se	-
	NST D +P	0%
***Short Run* Premature Ventricular Contraction (*PVC*)[1]**	**E Se**	78%
	E +P	95%
	Avg E Se	60%
	Avg E +P	80%
***Long Run* Premature Ventricular Contraction (PVC)[1]**	**E Se**	39%
	E +P	94%
	Avg E Se	71%
	Avg E +P	91%

[1] *PVC Runs are not displayed or reported in Polysmith Software.*

E: Episode
D: Duration
+P: Predictivity, the fraction of detections that are events
Se: Sensitivity, the fraction of events that are detected
Avg: Average
NST: Noise Stress Test Database

Results Discussion

Testing shows that the arrhythmia detection results are comparable to the already registered reference device, BSM 9100A Series Nihon Kohden Bedside Monitor (K082785), which includes the same algorithm. Since the BSM-9100A is much more critical in nature, comparable results are considered acceptable for the scope and intended use of the Polysmith software.

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 NTI7593 presents no new questions of safety and effectiveness and, is substantially equivalent to the features provided by the identified predicate.