K131415

## 510(k) Summary

**SUMMARY DATE:**

Monday May 13, 2013

AUG 09 2013

**510K 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: david.pezet@neurotronics.com
Title: Quality Manager
Phone: 352.372.9955 Ext 355


***Establishment Registration Number:***
1063925

**DEVICE TYPE (COMMON NAME):**

Non-Normalizing Quantitative Electroencephalograph Software

**PROPRIETARY NAME OF THE DEVICE:**

Live View Panel (LVP)

CLASSIFICATION:

*Product Code:*

| Product Code | Device | Regulation Description | Regulation Number |
|---|---|---|---|
| GWQ | Full-Montage Standard Electroencephalograph | Electroencephalograph | 882.1400 |

Subsequent Product Code:

| Product Code | Device | Regulation Description | Regulation Number |
|---|---|---|---|
| OLZ | Automatic Event Detection Software For Polysomnograph With Electroencephalograph | Electroencephalograph | 882.1400 |
| OLV | Standard Polysomnograph With Electroencephalograph | Electroencephalograph | 882.1400 |
| OLT | Non-Normalizing Quantitative Electroencephalograph Software | Electroencephalograph | 882.1400 |

PREDICATE DEVICES

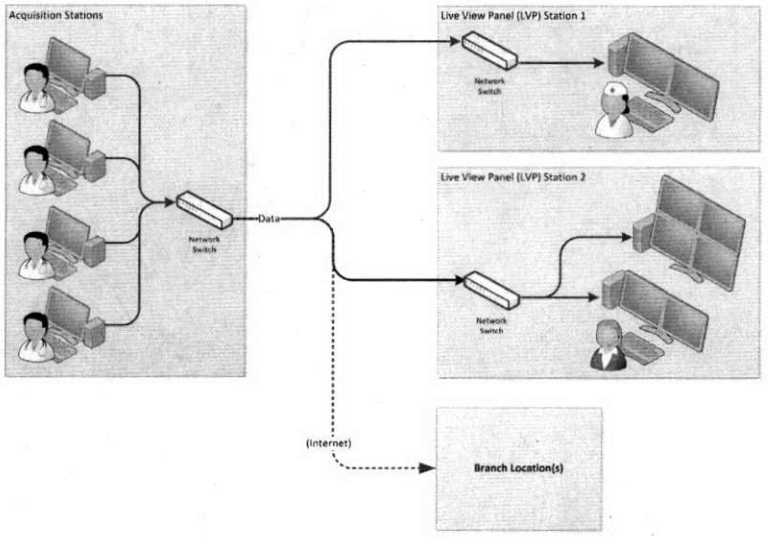
| Submitter/Holder | Device Name | Model | 510(K) |
|---|---|---|---|
| Nihon Kohden America, Inc. | Nihon Kohden EEG-1200A Series Neurofax | EEG-1200A | K080546 |
| Neurotronics, Inc. | Polysmith Sleep System | NTI5498 | K062943 |
| Nihon Kohden Corp. | PSG-1100 Sleep Diagnostic System | PSG-1100 | K120888 |
| Nihon Kohden America, Inc. | Nihon Kohden EEG-1200A with JE-120A Multi Channel Electrode Junction Box | JE-120A | K113117 |

## DESCRIPTION

The Live View Panel (LVP) consists of several software components that allow remote viewing of digitized physiological waveforms and general patient information for the purpose of viewing EEG (electroencephalography) or PSG (polysomnography) patients in real time or in review. The software uses off-the-shelf and custom software components to manage multiple computer displays to facilitate the viewing of several patients simultaneously.

The Live View Panel consists of three software components. The Live View Panel Acquisition Interface Server (AIS) located on the acquisition system collects patient data from a recording machine and transmits this information over a network to a client machine. The Live View Panel client program receives this information and displays basic information in grid pattern along with other patients. The Live View Panel Monitor Controller program manages a bank of displays, each displaying a single patient. The Live View Panel grid mimics the physical locations of the monitors to allow the clinician manage and keep track of multiple patients displayed on the bank of displays.

The Live View Panel is software only and does not connect to the patient except through a cleared and currently marketed EEG or PSG device. A software module resides on the EEG or PSG device and sends patient data to a remote computer where another software module displays the data on an array of monitors. The software runs on off-the-shelf computers.



## INTENDED USE

The Live View Panel is an accessory to EEG and PSG systems, intended to transmit EEG or PSG data to a remote location where the data can be viewed by a clinician to aid in diagnosis of epilepsies, sleep disorders, and other related disorders.

The Live View Panel is intended for use by medical personnel within a medical facility, clinic or nursing home, or outside a medical facility under the supervision of a medical professional. The Live View Panel is available for use on all patient populations, including adults and children as determined by the medical professional.

This device is not to be used to monitor life threatening situations.

This device is not to be used to control life supporting or life sustaining devices.

PREDICATE COMPARISON

### *Intended Use Comparison*

The Live View Panel accessory improves upon the predicates' current capabilities for remote access and review of on-line or previously recorded acquisitions. This accessory does not change the indications for use for the devices which it is an accessory. This accessory is intended to aid in diagnosis of epilepsies, sleep disorders, and other related disorders.

### *Technical Comparison*

The Live View Panel contains a subset of features found in the predicate. The device's main function is to facilitate the viewing of multiple patients' data from a location physically removed from the patient area. The Live View Panel extends the predicates' ability to view recordings remotely by providing an intuitive interface to manage multiple recordings. Therefore Neurotronics believes the Live View Panel is substantially equivalent to the Nihon Kohden EEG-1200A with JE-120A Multi Channel Electrode Junction Box (K113117), Nihon Kohden EEG-1200A Series Neurofax (K080546), PSG-1100 Sleep Diagnostic System (K120888), and Polysmith Sleep System, Model NTI5498 (K062943).

| Live View Panel | EEG Predicates (K113117 , K080546) | PSG Predicates (K062943 , K120888) |
|---|---|---|
| Display Electrical activity of the brain and other physiological signals on a monitor | Same | Same |
| Device uses Windows™ on a 32-bit computer | Same | Same |
| Display waveforms in acquisition and review | Same | Same |
| Maximum number of waveforms on screen is 64 (EEG) and 32 (PSG) | Same | Same |
| Simultaneously view waveforms from multiple EEG/PSG instruments connected to a network and display values from external instruments | Same | Same |
| Variable waveform display duration | Same | Same |
| Change waveform parameters (pattern, montage, amplifier conditions, AV induction) | Same | Same |
| Add, edit, delete on screen events | Same | Same |
| The device can measure vital signs (including ECG, EMG, Respiration, ocular motility, SpO2, and CO2) | Same | Same |
| Display patient video along with waveforms | Same | Same |
| For use by medical personnel in a medical facility, physician's office, laboratory, clinic, or nursing home | Same | Same |
| Any patient population including adults and children as determined by a trained professional | Same | Same |

## PERFORMANCE DATA

### *Testing Data*

Testing included: Software testing

## CONCLUSION

Based on the results of the Intended Use Comparison, the Technical Comparison, and Testing Data, it is believed that the Live View Panel (LVP) accessory presents no new questions of safety and effectiveness and, is substantially equivalent to the features provided by the Nihon Kohden EEG-1200A with JE-120A Multi Channel Electrode Junction Box (K113117), Nihon Kohden EEG-1200A Series Neurofax (K080546), Polysmith Sleep System, Model NTI5498 (K062943), and PSG-1100 Sleep Diagnostic System (K120888).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

August 9, 2013

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

Re: K131415
Trade/Device Name: Live View Panel
Regulation Number: 21 CFR 882.1400
Regulation Name: Standard polysomnograph with electroencephalograph
Product Code: OLV, GWQ, OLZ, and OLT
Dated: June 16, 2013
Received: June 17, 2013

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting 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): K131415

Device Name: Live View Panel (LVP)

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K131415