K110376

510(K) SUMMARY

JUL 29 2011

- **Name and Address of Applicant**

Nihon Kohden America, Inc.
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Foothill Ranch, Ca 92610

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Attn: Steve Geerdes, Director of Regulatory Affairs

Date: July 20th , 2011

- **Name/Trade Name of the Device:** Nihon Kohden PE-210AK Switch Box for EEG-1200A

- **The common or usual Name:** Electroencephalograph (EEG)

- **The Classification:** The device has been classified as Class II by the Neurology Device Classification Panel under 21 CFR Part 882.1400 Electroencephalograph per GWQ.

- **The legally marketed equivalence:** The predicate device is the Excel Tech EMU 128s Switch Matrix commercial distribution March 12, 2004 cleared under 510k # K040360

- **A description of the device:**

  The PE-210A Switch Box is an optional accessory for the EEG-1200A device cleared under 510k # k080546. The PE-210AK Hardware is made up of electronic switches inside a box enclosure and cable connections on the outside of the box enclosure. The PE210AK Hardware switch box does not have any controls or adjustment for the operator. All settings, controls, and adjustments are made using the PE-210AK software installed on the EEG's (off the shelf) PC. Utilizing the EEG's CPU, Data storage, keyboard, mouse, and display, the PE-210AK switch box software allows the user switch electrode stimulation sites between the EEG recording and the cortical stimulator. The PE-210AK software allows the user to query the data recorded on the EEG's PC and create a report of the stimulation sites, including duration and intensity settings.

The PE-210AK Software Program contains the following capabilities;

(1) Acquisition
- Electrodes can be arranged on the brain map image.
- Image files (JPEG/BMP/TIF) can be used for the brain map image.
- STIM SITE (+) and STIM REF (-) electrodes switched for stimulation can be selected.
- Identification when the stimulation electrodes are selected:
  STIM SITE (+) -> Red
  STIM REF (-) -> Blue

Names of the selected electrodes are displayed outside the brain map image.
- Zoom display of electrode frames and electrode names
- Current value (intensity) of stimulation of the electric stimulator can be set for the stimulation event.

- Duration time for switching electrodes for stimulation (train duration, max 300sec) can be set.
- Switching electrodes for stimulation can be started or stopped with the mouse or the space key.
- State of being stimulating can be easily recognized by the START button highlighted in fluorescent color.
- Comments can be entered and stimulation events can be registered.
- The table of stimulation events including names of the selected stimulation electrodes and current values can be displayed.
- Trigger signal (stimulation rate/trigger pulse width/train) can be set.
- Equipped with the symbols for the functional map and the functional mapping report can be created simultaneously.
- Symbols can be added arbitrarily by a user.
- The functional mapping report and the table of stimulation events can be saved in a file.
- Equipped with the automatic file backup function
- The functional mapping report and the table of stimulation events can be printed.

(2) Review
- The functional mapping report can be edited.
- Comments can be entered and stimulation events can be reviewed and edited.
- The table of stimulation events including names of the selected stimulation electrodes and current values can be displayed.
- The functional mapping report and the table of stimulation events can be printed.

(3) Others
- Operation method is based on Windows (GUI/mouse/keyboard).
- Files can be read and written on the network.
- Equipped with the check-up program for the switch/trigger signals

- **Intended Use**

  EEG- 1200A Series Neurofax is intended to record, measure and display cerebral and extracerebral activity for EEG and Sleep Studies. These data may be used by the clinician in Sleep Disorder, Epilepsies and other related disorders as an aid in diagnosis.

  The PE-210AK Switch Box is an optional accessory for the EEG-1200A device. It is used with the EEG-1200A to switch between EEG recording and cortical stimulation using the same cortical electrode. The software is used for functional brain mapping to support diagnostic and surgical epilepsy procedures.

  The device is intended for use within a hospital or medical facility under direct supervision of a medical professional

- **A summary of the technological characteristics of the device compared to the predicate device:**

The new PE-210AK Switch Box is connected between the multi-channel electrode junction box (JE-0011/0012/0013 and switches the connection destination of signal lines of electrodes between the electroencephalograph and the external stimulation unit (only one pair of electrodes can be switch at a time). The switch box is controlled by the switch box software which is installed on the electroencephalograph (EEG). Both the EMU128s and the PE-210AK have a hardware switch box and software controls that allow electrodes to be switched between the stimulation unit and the EEG device.

COMPARATIVE INFORMATION

Software Capabilities/ Characteristics

New Device	Predicate	
PE-210AK Switch Box	Excel Tech's EMU 128S Switch Matrix	
Switch output from a Stimulation Unit to EEG electrodes connected to the patient and the EEG instrument	Same	
Stimulated site manually selected by user	Same	
Data may be used by the clinician to aid in diagnosis.	Same	
For use by medical personnel.	Same	
For use functional mapping Measurement.	Same	
Electrodes can be arranged on the brain map image	Same	
Image files (JPEG/BMP/TIF) can be used for the brain map image	Same	
STIM SITE (+) and STIM REF (-) electrodes switched for stimulation can be selected	Same	
Identification when the stimulation electrodes are selected: STIM SITE (+) -> Red STIM REF (-) -> Blue	Same	
Names of the selected electrodes are displayed outside the brain map image.	Same	
Zoom display of electrode frames and electrode names	No	This is just a zoom in feature. There is no impact on patient safety or effectiveness of device.

Switching electrodes for stimulation can be started or stopped with the mouse or the space key.	Same	
State of being stimulating can be easily recognized by the START button highlighted in fluorescent color.	Same	
Comments can be entered and stimulation events can be registered.	Same	
The table of stimulation events including names of the selected stimulation electrodes and current values can be displayed.	No Current Values just electrode Names	All values are registered including Electrode names, Intensity and Duration
The functional mapping report and the table of stimulation events can be saved in a file.	Same	Only when entered as comment
Equipped with the automatic file backup function	Same	
The functional mapping report and the table of stimulation events can be printed.	Same	Only when entered as comment
The functional mapping report can be edited in Review Mode.	Same	Only when entered as comment
Comments can be entered and stimulation events can be reviewed and edited.	Same	
The table of stimulation events including names of the selected stimulation electrodes and current values can be displayed	Same	Only when entered as comment
The functional mapping report and the table of stimulation events can be printed.	Same	Only when entered as comment
Operation method is based on Windows (GUI/mouse/keyboard).	Same	
Files can be read and written on the network.	Same	Only comments
Equipped with the check-up program for the switch/trigger signals	No	This feature has No impact on effectiveness of device. Tool to assure proper operation.

Physical (Hardware) Characteristics

PE-210AK Switch Box	EMU 128S Switch Matrix	Comments
Electronic Switch	Same	Controlled by software
Trigger out for external Stimulator is available.	Same	

Switch output from a Stimulation Unit to EEG electrodes connected to the patient and the EEG instrument.	Same	
Creates report for functional mapping. (Use a EEG PC Unit)	Same	
Prints report for functional mapping. (Printed by Printer with EEG's PC)	Same	

Target Population

PE-210AK Switch Box	EMU 128S Switch Matrix	Comments
1. Any location within a medical facility, physician's office, Laboratory or clinic.	Same	
2. May be used in the intensive care unit or operating room for Monitoring or recording.	Same	
3. Any patient population (including adults and children) as determined by Trained professionals.	Same	

The device is not sterile.

The device is not contacting patients. Therefore, no good laboratory practice studies were required per 21 CFR 58.

Design validation confirmed the operation of the software and hardware of the device is in accordance to the design specifications.

The device was subjected to electromagnetic, environmental, safety and performance testing procedures. These test verified the proper operation of the device. Design validation confirmed the operation of the software and hardware of the device is in accordance to the design specifications.

Therefore based on the above, Nihon Kohden believes that the PE-210AK is substantially equivalent to the Excel Tech EMU 128s Switch Matrix cleared under 510k # K040360.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Nihon Kohden Corporation
c/o Steve Geerdes
Director of Regulatory Affairs
90 Icon Street
Foothill Ranch, CA 92610

JUL 29 2011

Re: K110376
Trade/Device Name: Nihon Kohden PE-210AK Switch Box for EEG 1200A
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ and GYC
Dated: November 30, 2010
Received: February 09, 2011

Dear Mr. Geerdes:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): ___K110376_____

Device Name: ___PE-210AK Switch Box___

Indications for Use:

EEG- 1200A Series Neurofax is intended to record, measure and display cerebral and extracerebral activity for EEG and Sleep Studies. These data may be used by the clinician in Sleep Disorder, Epilepsies and other related disorders as an aid in diagnosis.

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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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

_____
Division Sign-Off
Office of Device Evaluation

510(k)_____

_____
(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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