**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
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May 19, 2017

Nihon Kohden Corporation
% Tom Bento
Sr. Vice President, Quality and Regulatory
Nihon Kohden America, Inc.
15353 Barranca Parkway
Irvine, California 92618

Re: K163644
Trade/Device Name: Nihon Kohden QP-160AK EEG Trend Program
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMB, OMA, OLT, ORT
Dated: April 21, 2017
Received: April 21, 2017

Dear Mr. Bento:

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,

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)*
K163644

Device Name
Nihon Kohden QP-160AK EEG Trend Program

Indications for Use *(Describe)*
The QP-160AK EEG Trend Program is a software-only device intended to calculate and display EEG data obtained from the Nihon Kohden specified host device. The QP-160AK is intended to be used by qualified medical practitioners, trained in electroencephalography, who will exercise professional judgment when using the information.
The intended use is as follows:
• The EEG and aEEG waveforms are intended to help the user monitor the state of the brain.
• The user-defined Fast Fourier Transform (FFT) parameters of this software (FFT power) are intended to help the user analyze the EEG waveform.
• The burst suppression parameters of this software (interburst interval and bursts per minute) are intended to aid in the identification and characterization of areas of burst-suppression pattern in the EEG.
• The seizure detection component of QP-160AK is intended to mark previously acquired EEG waveforms of adult (greater than or equal to 18 years) that may correspond to electrographic seizures in order to aid in identification of seizure events and help review and annotation of EEG traces by user. EEG should be recorded with full scalp montage at the standard 10/20 system. The notifications for seizure detection are provided. QP-160AK notifications cannot be used as a substitute for real time monitoring of the underlying EEG by a trained expert.
This device does not provide any diagnostic conclusion about the patient's condition to the user.
The device is intended for use by medical personnel in any location within a medical facility, laboratory, clinic or nursing home or outside of a medical facility under direct supervision of a medical professional.

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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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary for Nihon Kohden EEG Trend Program QP-160AK


| | |
|---|---|
| Submitter: | Nihon Kohden Corporation |
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| Phone number: | 81-2-59968020 |
| Contact person: | Tom Bento |
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| | |
|---|---|
| Date prepared: | December 21, 2016 |
| Device name: | Nihon Kohden QP-160AK EEG Trend Program |
| Common name: | Electroencephalograph (EEG) |
| Primary product codes: | OMB, OLT, ORT, OMA |
| Regulation numbers: | 21 CFR 882.1400 |

Substantial equivalence claimed to: Nihon Kohden QP-160AK EEG Trend Program (K120485)
Persyst 12 EEG Review and Analysis Software (K133793)

**Description:**

The QP-160AK EEG Trend Program is a software-only device. When installed in Nihon Kohden neurology products with EEG measurement function, the device calculates and displays EEG data obtained from the neurology product's system. In addition, the QP-160AK EEG Trend Program identifies trends in the EEG data over extended periods of time in order for trained healthcare professionals to observe changes over time. Below is an illustration of how the device interacts with the Medical Personnel and Patient.

The program's existing main features are listed below:

- Calculate and display aEEG, DSA, FFT and burst suppression ratio trend
- Display up to 64 channel EEG
- Display $SpO_2$ and $ETCO_2$ trends
- Operation by touch panel buttons
- Data management with Neuro Workbench software

The modification is to add:

- Seizure detection and notification

**Indications for Use:**

The QP-160AK EEG Trend program is a software-only device intended to calculate, and display EEG data obtained from the Nihon Kohden specified host device. The QP-160AK is intended to be used by qualified medical practitioners, trained in Electroencephalography, who will exercise professional judgment when using the information.

The intended use is as follows:

- The EEG and aEEG waveforms are intended to help the user monitor the state of the brain.
- The user-defined Fast Fourier Transform (FFT) parameters of this software (FFT power) are intended to help the user analyze the EEG waveform.
- The burst suppression parameters of this software (interburst interval and bursts per minute) are intended to aid in the identification and characterization of areas of burst-suppression pattern in the EEG.
- The seizure detection component of QP-160AK is intended to mark previously acquired EEG waveforms of adult (greater than or equal to 18 years) that may correspond to electrographic seizures in order to aid in identification of seizure events and help review and annotation of EEG traces by user. EEG should be recorded with full scalp montage at the standard 10/20 system. The notifications for seizure detection are provided. QP-160AK notifications cannot be used as a substitute for real time monitoring of the underlying EEG by a trained expert.

This device does not provide any diagnostic conclusion about the patient's condition to the user.

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

**Technological Characteristics – Substantial Equivalence Discussion**

The Nihon Kohden QP-160AK EEG Trend Program is substantially equivalent to the predicate device of the same name (K120485) with the additional features of seizure detection and notification. For the seizure detection and notification, QP-160AK is substantially equivalent to the other listed predicate devices, Persyst 12 EEG Review and Analysis Software (K133793). Differences between the devices are minor and do not raise questions regarding safety or efficacy.

These differences include:

1. The QP-160AK EEG Trend Program is the same as the previous submission of QP-160AK cleared under K120485, but has two additional functions: seizure detection and notification of seizure detection.

2. For these new functions, we refer to Persyst 12 EEG Review and Analysis Software

(K133793) as the predicate.

3. Other functions of QP-160AK remain the same as the previously cleared submission, K120485; thus QP-160AK of K120485 is referenced as the predicate for the functions other than seizure detection and notification of seizure detection.

**Device Comparison**

| Specifications | Nihon Kohden QP-160AK | Persyst 12 EEG (Predicate device K133793) |
|---|---|---|
| **Indications for Use** | The QP-160AK EEG Trend program is a software-only device intended to calculate, and display EEG data obtained from the Nihon Kohden specified host device. The QP-160AK is intended to be used by qualified medical practitioners, trained in Electroencephalography, who will exercise professional judgment when using the information.<br><br>The intended use is as follows:<br><br>• The EEG and aEEG waveforms are intended to help the user monitor the state of the brain.<br>• The user-defined Fast Fourier Transform (FFT) parameters of this software (FFT power) are intended to help the user analyze the EEG waveform.<br>• The burst suppression parameters of this software (interburst interval and bursts per minute) are intended to aid in the identification and characterization of areas of burst-suppression pattern in the EEG.<br>• The seizure detection component of QP-160AK is intended to mark EEG waveforms of adult (greater than or equal to 18 years) that may correspond to | 1. Persyst 12 EEG Review and Analysis Software is intended for the review, monitoring and analysis of EEG recordings made by electroencephalogram (EEG) devices using scalp electrodes and to aid neurologists in the assessment of EEG. This device is intended to be used by qualified medical practitioners who will exercise professional judgment in using the information.<br><br>2. The Seizure Detection and Seizure Probability component of Persyst 12 is intended to mark previously acquired sections of adult (greater than or equal to 18 years) EEG recordings that may correspond to electrographic seizures, in order to assist qualified clinical practitioners in the assessment of EEG traces. EEG recordings should be obtained with a full scalp montage according to the standard 10/20 system.<br><br>3. The Spike Detection component of Persyst 12 is intended to mark previously acquired sections of the patient's EEG recordings that may correspond to spikes, in order to assist qualified clinical practitioners in the assessment of EEG traces. The Spike Detection component is intended to be used in patients at least one month old. Persyst 12 Spile |

| Specifications | Nihon Kohden QP-160AK | Persyst 12 EEG (Predicate device K133793) |
|---|---|---|
| | electrographic seizures in order to aid in identification of seizure events and help review and annotation of EEG traces by user. EEG should be recorded with full scalp montage at the standard 10/20 system. The notifications for seizure detection are provided.<br><br>This device does not provide any diagnostic conclusion about the patient's condition to the user.<br><br>The device is intended for use by medical personnel within a medical facility, laboratory, clinic or nursing home or outside of a medical facility under direct supervision of a medical professional. | Detection performance has not been assessed for intracranial recordings.<br><br>4. Persyst 12 includes the calculation and display of a set of quantitative measures intended to monitor and analyze the EEG waveform. These include FFT, Automatic event marking is not applicable to the quantitative measures. These quantitative EEG measures should always be interpreted in conjunction with review of the original EEG waveforms.<br><br>5. The aEEG functionality included in the Persyst 12 is intended to monitor the state of the brain. The automated event marking function of Persyst 12 is not applicable to aEEG.<br><br>6. Persyst 12 provides notifications for seizure detection, quantitative EEG and aEEG that can be used when processing a record during acquisition. These include an on screen display and the optional sending of an email message. Delays of up t several minutes can occur between the beginning of a seizure and when the Persyst 12 notifications will be shown to a user. Persyst 12 notifications cannot be used as a substitute for real time monitoring of the underlying EEG by a trained expert.<br><br>7. Persyst AR (Artifact Reduction) is intended to reduce EMG, eye movement, and electrode artifacts in a standard 10-20 EEG recording. AR does not remove the entire artifact signal, and is not effective for other types of artifacts. AR may modify portions of waveforms representing cerebral activity. Waveforms must still be read by a qualified medical |

| Specifications | Nihon Kohden QP-160AK | Persyst 12 EEG (Predicate device K133793) |
|---|---|---|
| | | practitioner trained in recognizing artifact, and any interpretation or diagnosis must be made with reference to the original waveforms.<br><br>8. This device does not provide any diagnostic conclusion about the patient's condition to the user. |
| **Identify Seizures** | Yes | Yes |
| **Provides Seizure Notifications** | Yes | Yes |
| **Identify Spikes** | No | Yes |
| **Montage/Channel Array** | Scalp 10/20 Array | Scalp 10/20 Array |
| **Number of EEG Channels** | Up to 32/64 EEG channels (dependent on amplifier) | Up to 32/64 EEG channels (dependent on amplifier) |
| **Number of DC Channels** | Up to 8 channels (dependent on amplifier) | Up to 8 channels (dependent on amplifier) |
| **Density Spectral Array (DSA) Trend** | Yes | Yes |
| **Density Spectral Array (DSA) Asymmetry Trend** | Yes | Yes |
| **Spectral Edge Frequency Trend** | Yes | Yes |
| **Amplitude Integrated EEG (aEEG) Trend** | Yes | Yes |
| **Burst Suppression Ratio (BSR) Trend** | Yes | Yes |
| **Inter-Burst Interval (IBI) Trend** | Yes | No |
| **Burst Per Minute (BPM) Trend** | Yes | No |
| **FFT Power Trend** | Yes | Yes |
| **FFT Power Asymmetry Trend** | Yes | Yes |
| **FFT Power ratio (e.g. Alpha/Delta, Alpha/Beta) Trend** | Yes | Yes |
| **External Input (DC Input) Display** | Yes | Yes |
| **Number of Trends** | More than 16 | More than 16 |
| **User Selectable Trend Group (Panel)** | Yes | Yes |
| **Time Interval of Trends** | 1 minute/page to 24 hours/page, 1cm/hour to 300cm/hour | 1 minute/page to 24 hours/page, 1cm/hour to 60cm/hour |
| **User Selectable Trends Time Scale** | Yes | No |

| Specifications | Nihon Kohden QP-160AK | Persyst 12 EEG (Predicate device K133793) |
|---|---|---|
| **Annotation List** | Yes | Yes |
| **Raw EEG data display look-back while recording synchronized video** | Yes | Yes |

**Test Summary:**

Performance testing for the QP-160AK includes software verification tests, system validation tests, and seizure detection performance tests. Traceability has been documented between all system specifications to validation test protocols.

Verification and validation testing includes:

1. Code inspections
2. Unit level testing
3. Integration level testing
4. System level testing
5. Seizure detection performance testing: The testing was performed using archived EEG recordings obtained from 139 patients of 18 years and older admitted to an Epilepsy Monitoring Unit. All EEG data were recorded with full scalp montage using the standard 10/20 system. Each recording lasts approximately 4 hours for a total of 556 hours of EEG recording. All 139 recordings were manually annotated by three independent EEG experts and the clinical reference standard (ground truth) was determined by using a two-third majority rule. Total 145 seizures were identified. The same EEG recordings were used for seizure detection by the QP-160AK EEG Trend Program and the results were compared against the ground truth by calculating Positive Percent Agreement (PPA) and False Detection Rate (FDR) as below:

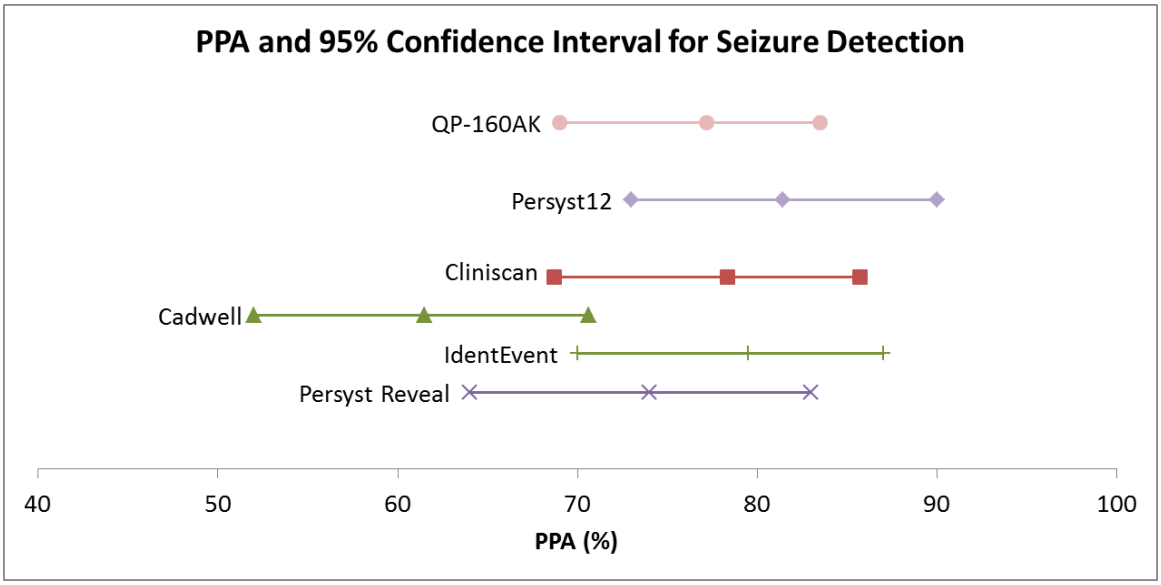
$$\text{PPA} = \frac{True\ Positives}{True\ Positives + \ False\ Negatives}$$

$$\text{FDR} = \frac{False\ Positives}{hour\ of\ EEG\ Recording}$$

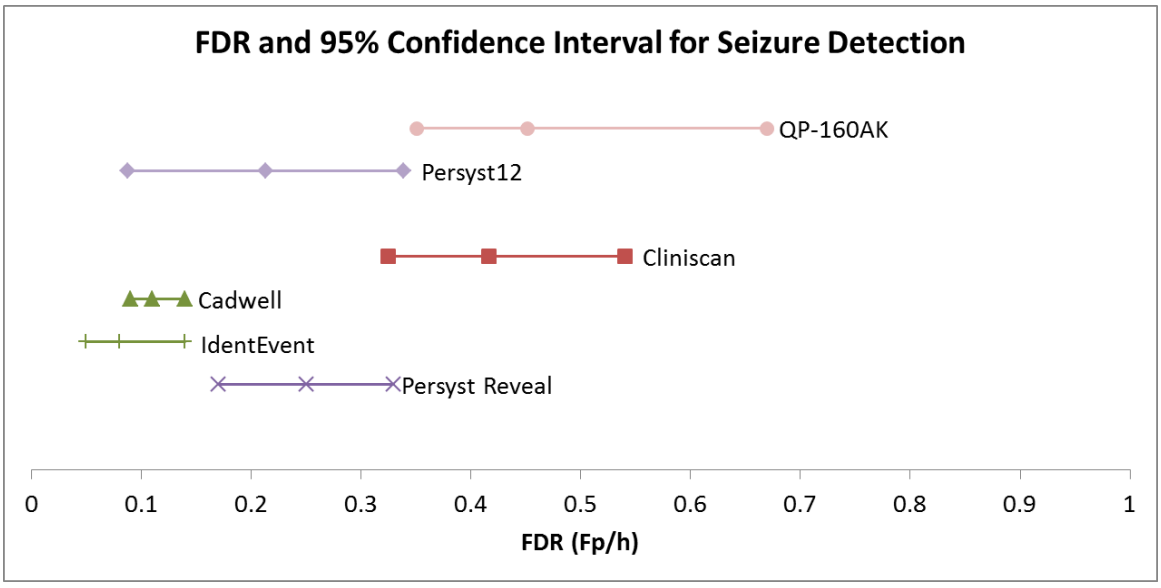
The following mean and 95% Confidence Intervals using bootstrap method were obtained:

| Performance Statistics | Mean | 95% CI |
|---|---|---|
| Positive Percent Agreement (%) | 77.2 | 69.0 - 83.5 |
| False Detection Rate (FDR) | 0.451 | 0.320 - 0.669 |

**Comparison of Positive Percent Agreement and 95% Confidence Interval**




**Comparison of False Detection Rate and 95% Confidence Interval**




**Conclusion:**

The performance of the Nihon Kohden QP-160AK EEG Trend Program is substantially equivalent to the predicate devices, the Nihon Kohden QP-160AK EEG Trend Program (K120485) and Persyst 12 EEG Review and Analysis Software (K133793), and raises no safety or effectiveness issues.