



October 9, 2025

Nihon Kohden Corporation  
% Charlemagne Chua  
Senior Manager, Regulatory Affairs  
Nihon Kohden America, LLC  
15353 Barranca Parkway  
Irvine, California 92618

Re: K251366

Trade/Device Name: EEG-1260A Neurofax System (EEG-1260A); JE-940A EEG Amplifier Unit (JE-940A); LS-940A Photic Stimulator (LS-940A)

Regulation Number: 21 CFR 882.1400

Regulation Name: Electroencephalograph

Regulatory Class: Class II

Product Code: OLT, GWQ, OLV, GWE

Dated: September 12, 2025

Received: September 12, 2025

Dear Charlemagne Chua:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory->

[assistance/contact-us-division-industry-and-consumer-education-dice](#)) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
**Patrick Antkowiak -S**

for

Jay Gupta

Assistant Director

DHT5A: Division of Neurosurgical,  
Neurointerventional, and  
Neurodiagnostic Devices

OHT5: Office of Neurological and  
Physical Medicine Devices

Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K251366

Device Name

EEG-1260A Neurofax System (EEG-1260A);  
JE-940A EEG Amplifier Unit (JE-940A);  
LS-940A Photic Stimulator (LS-940A)

Indications for Use (Describe)

EEG-1260A Neurofax System

The EEG-1260A 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 disorders, epilepsies and other related disorders as an aid in diagnosis. 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.

JE-940A EEG Amplifier Unit

The EEG amplifier unit is intended to acquire and record the EEG and other biological signals (ECG, EMG, respiration, EOG, snoring, body position, SpO<sub>2</sub>, pulse waveform) of a patient, and transmit the measurement data to the electroencephalograph. The transmitted measurement data is displayed on the electroencephalograph screen and provides information to evaluate the functional state of the brain, brain-related diseases and disorders, and sleep disorders.

The device is intended for use by qualified medical personnel within a medical facility, or by staff in an equivalent facility under the direct supervision of qualified medical personnel.

The device is available for use on any patient as determined by qualified medical personnel.

LS-940A Photic Light

The photic stimulator is a light source for photic stimulation to confirm the responsiveness of EEG to photic stimulation during EEG tests and to test visual evoked potentials.

The device is intended for use by qualified medical personnel within a medical facility, or by staff in an equivalent facility under the direct supervision of qualified medical personnel.

The device is available for use on any patient as determined by qualified medical personnel.

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)

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### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## 510(k) SUMMARY

### Administrative Information

**Sponsor:** Nihon Kohden Corporation  
1-31-4 Nishiochiai, Shinjuku-Ku  
Tokyo, Japan 161-8560  
FDA Est. Registration: 9611252

**Submitter:** Nihon Kohden America, LLC  
15353 Barranca Parkway  
Irvine, CA 92618  
FDA Est. Registration: 2080783

**Primary Correspondent /U.S. Agent:** Charlemagne Chua  
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15353 Barranca Parkway  
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### Subject Device Information

**Submission Type:** Traditional 510(k)

**Common Device Name:** Non-Normalizing Quantitative  
Electroencephalograph Software

**Regulation Medical Specialty:** Neurology

**Classification Panel:** Neurology

**Product Codes:** OLT, GWQ, OLV, GWE

**Premarket Review:** Office of Neurological and Physical Medicine  
Devices (OHT5)  
Neurosurgical, Neurointerventional and  
Neurodiagnostic Devices (DHT5A)

**Regulation Number:** 882.1400

**Classification:** Class II

**Decision Type:** 510(k)

**Traditional 510(k) – EEG-1260A Neurofax System  
510(K) Summary**

**Proprietary Name:** EEG-1260A Neurofax

**Reason for 510(k) Submission:** Modification to an Existing Device and Introduction of New Accessories

**Original 510(k) / Predicate:** EEG-1200A Series Neurofax (K080546)

**Predicate Manufacturer:** Nihon Kohden Corporation

**Submission Date:** October 3, 2025

## 1. PRODUCT DESCRIPTION

The EEG-1260A Neurofax is an electroencephalograph system specifically designed for use in healthcare facilities. This device is designed to measure and display the patient's electroencephalogram (EEG) and polysomnography (PSG) signals, providing information and analysis of brain electrical activity.

The JE-940A EEG amplifier unit is a new amplifier unit and is an input unit of the EEG-1260A. The JE-940A Amplifier unit acquires and measures EEG and other polysomnography signals (ECG, EMG, respiration, EOG, snoring, body position, SpO<sub>2</sub>, and pulse waveforms) associated with EEG/PSG testing, and transmits the acquired data to the EEG-1260A Neurofax. The JE-940A operates on AC power or on battery power for mobile EEG measurements. The JE-940A offers an option to connect with the JE-944A Mini electrode junction box, which enhances the operational efficiency and mobility in EEG measurements.

The LS-940A Photic stimulator is a device which provides visual stimuli in the form of flashing light and is used to assess a patient's EEG responses to light stimulation. The parameters for flashing the light signal are controlled by the EEG-1260A Neurofax.

## 2. INDICATION FOR USE / INTENDED USE

### EEG-1260A

Intended Use: The EEG-1260A Electroencephalographs record electroencephalogram and related vital signals and displays the electroencephalogram and vital signals as waveforms.

Indication for Use: The EEG-1260A 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 disorders, epilepsies and other related disorders as an aid in diagnosis. 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.

### JE-940A

Intended Use: The JE-940A amplifier unit is intended to acquire and record the EEG and other biological signals (ECG, EMG, respiration, EOG, snoring, body position, SpO<sub>2</sub>, pulse waveform) of a patient, and transmit the measurement data to the electroencephalograph.

Indication for Use: The EEG amplifier unit is intended to acquire and record the EEG and other biological signals (ECG, EMG, respiration, EOG, snoring, body position, SpO<sub>2</sub>, pulse waveform) of a patient, and transmit the measurement data to the electroencephalograph. The transmitted measurement data is displayed on the electroencephalograph screen and provides information to evaluate the functional state of the brain, brain-related diseases and disorders, and sleep disorders.

The device is intended for use by qualified medical personnel within a medical facility, or by staff in an equivalent facility under the direct supervision of qualified medical personnel.

The device is available for use on any patient as determined by qualified medical personnel.

**LS-940A**

Intended Use: LS-940A is intended to evoke response photic stimulator.

Indication for Use: The photic stimulator is a light source for photic stimulation to confirm the responsiveness of EEG to photic stimulation during EEG tests and to test visual evoked potentials.

The device is intended for use by qualified medical personnel within a medical facility, or by staff in an equivalent facility under the direct supervision of qualified medical personnel.

The device is available for use on any patient as determined by qualified medical personnel.

**3. SUBMISSION SCOPE**

Nihon Kohden (NK) is requesting market clearance for a modified Nihon Kohden device, the EEG-1260A Neurofax and newly introduced accessories. The new accessories of the EEG-1260A Neurofax include the JE-940A EEG Amplifier Unit and LS-940A Photic Stimulator.

**4. COMPARISON WITH THE PREDICATE DEVICES**

**4.1 Subject Device Information**

Table 1 provides the regulation and classification for the subject device and accessories.

**Table 1 Regulatory Information on EEG-1260A, JE-940A, and LS-940A**

Device	Regulation	Product Code	Device Classification	Classification
EEG-1260A	§882.1400	OLT, GWQ, OLV, GWE	Non-Normalizing Quantitative Electroencephalograph Software	Class II
JE-940A	§882.1400	GWQ, OLV, OLT	Full-Montage Standard Electroencephalograph	Class II
LS-940A	§882.1890	GWE	Stimulator, Photic, Evoked Response	Class II

## 4.2 Predicate Device Information

Table 2 lists the basic information about the predicate devices including 510(k) number, device name, 510(k) holder, and clearance date. Regulatory information used for comparison is provided in Table 3

**Table 2 Predicate Device General Information**

Device	Predicate/Reference Device General Information			
	510(k) Number	Device Name	510(k) Holder	Clearance Date
EEG-1260A	K080546	EEG-1200A Series Neurofax	Nihon Kohden Corp.	August 29, 2008
JE-940A	K080546	JE-921A Electrode Junction Box	Nihon Kohden Corp.	August 29, 2008
LS-940A	K101691	Lifelines Photic Stimulator	Lifelines Ltd.	August 10, 2010

**Table 3 Predicate Device Regulatory Information**

Device	Regulation	Product Code	Device Classification	Classification
EEG-1200A	§882.1400	OLT, GWQ, OLV	Non-Normalizing Quantitative Electroencephalograph Software	Class II
JE-921A	§882.1400	GWQ, OLV	Full-Montage Standard Electroencephalograph	Class II
Lifelines Photic Stimulator	§882.1890	GWE	Stimulator, Photic, Evoked Response	Clas II

### 4.3 Comparison Table

**Table 4 Comparison Table of the EEG-1260A Neurofax and its Predicate**

Description	EEG-1260A <i>Subject Device</i>	EEG-1200A (K080546) <i>Predicate Device</i>	Comment
<b>General</b>			
Manufacturer (Applicant)	Nihon Kohden Corporation	Nihon Kohden Corporation	No change
Classification panel	Neurology	Neurology	No change
Device class	Class II	Class II	No change
Regulatory number	21 CFR Part 882.1400	21 CFR Part 882.1400	No change
Product code	OLT, GWQ, OLV	OLT, GWQ, OLV	No change
Indications for use	The EEG-1260A 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 disorders, epilepsies and other related disorders as an aid in diagnosis. 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.	The 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 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.	No change*  *Note: after K080546 was FDA cleared, EEG-1200A was renamed as EEG-1260A.
Intended use	The EEG-1260A Electroencephalographs record electroencephalogram and related vital signals and displays the electroencephalogram and vital signals as waveforms.	Not Specified	No change
Intended Population	Patient age not specified	Patient age not specified	No change
<b>Cybersecurity</b>			
Cybersecurity	Comply with FDA guidance <i>Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (2023)</i>	Not embedded	Change

Traditional 510(k) – EEG-1260A Neurofax System  
510(K) Summary

Description	EEG-1260A <i>Subject Device</i>	EEG-1200A (K080546) <i>Predicate Device</i>	Comment
Cybersecurity - Protection data	Encryption function complies with FIPS 140-2 Level.1	Not embedded	Change
<b>Compatible Input Unit</b>			
EEG amplifier	JE-940A (New)	JE-921A JE-120A (K113117) WEE-1200 (K171124) AE-120A (K183529)	Change The predicate device is available with the <i>same optional compatible amplifier(s)</i> as with the subject device through the 510(k) clearance K113117, K171124, K183529.
<b>Function (Software)</b>			
PE-210AK, Switch Box Program	<i>Available</i>	<i>Not Available at the time of K080546 clearance.</i>	<i>Change</i>
Identification and characterization of areas of burst-suppression pattern in the EEG.	Available (Optional Software QP-160AK)	Not available at the time of K080546 clearance.	Change
Seizure detection	Available (Optional Software QP-160AK)	Not available at the time of K080546 clearance.	Change
Digital video software	Available (Optional Software QP-110AK)	Available (Optional Software QP-110AK)	No Change

**Table 5 Comparison Table of the JE-940A EEG Amplifier Unit and its Predicate**

Description	JE-940A <i>Subject Accessory Device</i>	JE-921A (K080546) <i>Predicate Device</i>	Comments
<b>General</b>			
Manufacturer	Nihon Kohden Corporation	Nihon Kohden Corporation	No Change
Product code	GWQ, OLV	GWQ, OLV	No Change
Indications for use	<p>The EEG amplifier unit is intended to acquire and record the EEG and other biological signals (ECG, EMG, respiration, EOG, snoring, body position, SpO2, pulse waveform) of a patient, and transmit the measurement data to the electroencephalograph. The transmitted measurement data is displayed on the electroencephalograph screen and provides information to evaluate the functional state of the brain, brain-related diseases and disorders, and sleep disorders.</p> <p>The device is intended for use by qualified medical personnel within a medical facility, or by staff in an equivalent facility under the direct supervision of qualified medical personnel.</p> <p>The device is available for use on any patient as determined by qualified medical personnel.</p>	Not clearly defined at the time of K080546 clearance.	Change
Intended use	<p>The JE-940A amplifier unit is intended to acquire and record the EEG and other biological signals (ECG, EMG, respiration, EOG, snoring, body position, SpO2, pulse waveform) of a patient, and transmit the measurement data to the electroencephalograph.</p> <p>JE-944A is intended to relay EEG and other vital signals to the JE-940A.</p>	Not clearly defined at the time of K080546 clearance.	Change

**Traditional 510(k) – EEG-1260A Neurofax System  
510(K) Summary**

Description	JE-940A <i>Subject Accessory Device</i>	JE-921A (K080546) <i>Predicate Device</i>	Comments
Prescription / Over-the-counter use	Prescription	Prescription	No Change
Intended population	Patient age not specified	Patient age not specified	No Change
<b>System Configuration</b>			
Compatible Junction Box	JE-922A Mini Electrode Junction Box JE-944A Mini Electrode Junction Box	JE-922A Mini Electrode Junction Box	Change
Connection method (Data transfer)	Wired communication: USB or LAN (Wired LAN: 100 BASE-TX)	Wired communication: USB or LAN	No Change
Connection security	Encryption method: AES-256 Encryption key: 256 bit (32 bytes)	Not embedded	Change
<b>Acquisition Features Parameters</b>	EEG, ECG, EMG, respiration, EOG, snoring, body position, SpO2, pulse waveform	EEG, ECG, EMG, respiration, EOG, snoring, body position, SpO2, pulse waveform, CO2	Change
Total number of inputs	63	49	Change
- EEG input jacks	25	25	
- Multi-purpose input jacks	16	4	
- Bipolar input jacks	16 (8 pairs) <u>(All bipolar input jacks can also be used as multi-purpose jacks)</u>	14 (7 pairs) (8 jacks (4 pairs) of bipolar input jacks can also be used as multi-purpose jacks)	
- DC input jacks	4	4	
- Body position channel	1	Not available	
- SpO2 connector	1	1	
- CO2 connector	Not available	1	
Sampling frequency	Select from the following: 4000 Hz, 2000 Hz, 1000 Hz, 500 Hz, 200 Hz	Select from the following: 1000 Hz, 500 Hz, 200 Hz, 100Hz	
Input impedance	200 MΩ	100 MΩ	
Internal noise level	Less than 1.5 μVp-p (0.5Hz to 60Hz)	Less than 1.5 μVp-p (0.5Hz to 60Hz)	
CMRR	120 dB or greater (EEG input, multi-purpose input) 100 dB or greater (bipolar input)	105 dB or greater (EEG input/extra input, 60Hz) 100 dB or greater (bipolar input, 60 Hz)	
Offset tolerance	±1000 mV or greater	±600 mV	
Input range	±1.6 mV, ±3.2 mV, or ±12.8 mV (selectable)	±3.2 mV	
A/D conversion	24 bits	16 bits	
Anti-aliasing filter	Select from the following:		

**Traditional 510(k) – EEG-1260A Neurofax System  
510(K) Summary**

Description	JE-940A <i>Subject Accessory Device</i>	JE-921A (K080546) <i>Predicate Device</i>	Comments
	1,200 Hz, 600 Hz, 300 Hz, 120 Hz, 70 Hz, 60 Hz	300 Hz	
Time constant	2 seconds (0.08 Hz) or 10 seconds (0.016 Hz) (selectable)	2 seconds	
EEG	Comply with IEC 80601-2-26:2019	Comply with IEC 60601-2-26:2002	Change
<b>Polysomnography Signals (Measurement Parameters other than EEG)</b>			
ECG	Linearity and dynamic range Amplitude of displayed waveform within 10 % of 50 $\mu$ V of the input signal (Input signal of triangular wave with amplitudes of 0.5 mV, 1 mV, 2 mV, and 6 mV p-v, 6.25Hz) Input impedance 10 M $\Omega$ or greater (5 mV sinusoidal signal with offset voltages of 300 mV and -300 mV, 10Hz) Common mode rejection At least 60 dB at the supply mains frequency (Sine wave, 50/60 Hz) At least 45 dB at twice the supply mains frequency (Sine wave, 100/120 Hz) System noise Not exceed 50 $\mu$ V p-v over any 10-second period	Linearity and dynamic range Amplitude of displayed waveform within 10 % of 50 $\mu$ V of the input signal (Input signal of triangular wave with amplitudes of 0.5 mV, 1 mV, 2 mV, and 6 mV p-v, 6.25Hz) Input impedance 10 M $\Omega$ or greater (5 mV sinusoidal signal with offset voltages of 300 mV and -300 mV, 10Hz) Common mode rejection At least 60 dB at the supply mains frequency (Sine wave, 50/60 Hz) At least 45 dB at twice the supply mains frequency (Sine wave and 100/120 Hz) System noise - Not exceed 50 $\mu$ V p-v over any 10-second period	No change
EMG	Amplitude of the displayed waveform is between 45 $\mu$ Vp-p and 55 $\mu$ Vp-p when a voltage of 10Hz and 50 $\mu$ Vp-p is applied.	Amplitude of the displayed waveform is between 45 $\mu$ Vp-p and 55 $\mu$ Vp-p when a voltage of 10Hz and 50 $\mu$ Vp-p is applied.	No change
Respiration (air flow)	Available (waveform)	Available (waveform)	No change
EOG	Amplitude of the displayed waveform is between 45 $\mu$ Vp-p and 55 $\mu$ Vp-p when a voltage of 10Hz and 50 $\mu$ Vp-p is applied.	Amplitude of the displayed waveform is between 45 $\mu$ Vp-p and 55 $\mu$ Vp-p when a voltage of 10Hz and 50 $\mu$ Vp-p is applied.	No change
Snoring	Available (waveform)	Available (waveform)	No change
Body position	Available	Available	No change
SpO2 declared range and pulse rate (PR)	SpO2 Declared range - 70 to 100%SpO2	SpO2 Declared range - 70 to 100%SpO2	Change

**Traditional 510(k) – EEG-1260A Neurofax System  
510(K) Summary**

Description	JE-940A <i>Subject Accessory Device</i>	JE-921A (K080546) <i>Predicate Device</i>	Comments
	Pulse Rate Display Range - 30 to 300 beats/min  Alarm - None  Comply with ISO 80601-2-61:2017	Alarm - None	Compliance to ISO 80601-2-61: 2017
Pulse waveform	Available	Available	No Change
CO2	Not Available	Optional	Change
Operating Mode			
Recording	The operation to start or stop data recording is available on both the device panel and from the electroencephalograph screen.	The operation to start or stop data recording is available only from the electroencephalograph screen.	Change
Data backup	Available	Not available	Change
Battery operation	Available Use of four AA batteries (alkaline primary batteries or NiMH secondary batteries).	Not available	Change
Lead check	Available	Not available	Change
Calibration data, log information (ISO 15189)	Available	Not available	Change
Environmental			
Operation conditions	Temperature 10 to 35°C (50 to 95°F) Humidity 30 to 85% (noncondensing) Atmospheric pressure 70 to 106 kPa	Temperature 10 to 35°C (50 to 95°F) Humidity 30 to 80% (noncondensing) Atmospheric pressure 70 to 106 kPa	Change
Storage conditions	Temperature -20 to +65°C (-4 to +140°F) Humidity 10 to 95% Atmospheric pressure 70 to 106 kPa	Temperature -20 to +60°C (-4 to +140°F) Humidity 10 to 80% Atmospheric pressure 70 to 106 kPa	No Change

**Table 6 Comparison Table of the LS-940A Photic Stimulator and its Predicate**

<b>Description</b>	<b>LS-940A Subject Accessory Device</b>	<b>Lifelines Photic Stimulator (K101691) Predicate Accessory Device</b>	<b>Comparison</b>
<b>Regulatory Information</b>			
Manufacturer	Nihon Kohden Corporation	LifeLines Ltd	Change
Product code	GWE	GWE	No Change
Indication for use	The photic stimulator is a light source for photic stimulation to confirm the responsiveness of EEG to photic stimulation during EEG tests and to test visual evoked potentials. The device is intended for use by qualified medical personnel within a medical facility, or by staff in an equivalent facility under the direct supervision of qualified medical personnel. The device is available for use on any patient as determined by qualified medical personnel.	The Lifelines Photic Stimulator is indicated for photic activation of the EEG during an EEG study and in the generation of visual evoked potentials.	Change
Intended use	LS-940A is intended to evoke response photic stimulator.	Not Specified	No change
Intended Population	Patient age not specified	Patient age not specified	No change
<b>Specification</b>			
Light source	LED	LED	No change
Illuminance Flash rate	- Typ. 26,000 lx / Single Manual flash (0.5 Hz, 1 to 33 Hz) - Typ. 26,000 lx (flash rate) 0.5 Hz, 1 to 33 Hz) - Typ. 13,800 lx (flash rate 40, 50, 60 Hz) (30 cm away from the light-emitting surface)	- 700 lm typical, 900 lm max - 13,000 lux at one 1 foot  1 to 60 Hz or single manual flash	Change
Frequency	- NORMAL 0.5, 1 – 33 (1Hz step), 40, 50, 60Hz - RANDOM 0.5, 1 – 33 (1Hz step)	The frequency is constant.	

## 5. PERFORMANCE

### 5.1 Summary of Non-Clinical Performance Testing

Nihon Kohden conducted non-clinical bench performance testing as part of the design verification and validation activities. The EEG-1260A, JE-940A, and LS-940A were evaluated for reprocessing & shelf-life, biocompatibility, software & firmware, cybersecurity & interoperability, electromagnetic compatibility & electrical, mechanical, wireless & thermal safety, system connection, and usability performance. The same test methods and specifications were used as for the predicate device, establishing equivalency with the predicate devices. The testing was conducted using EEG-1260A, JE-940A, and LS-940A as a system. These tests were performed according to the international and FDA-recognized consensus standards listed in [Table 7](#).

**Table 7 Applied Standards and Guidance List for the EEG-1260A, JE-940A, and LS-940A**

Recognition Number	Description
5-125	ISO 14971:2019 Medical devices - Application of risk management to medical devices
13-79	IEC 62304:2006+A1:2015 Medical device software -Software life cycle processes
13-122	IEC 81001-5-1: 2021 Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle
19-4	IEC 60601-1:2005+A1:2012+A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
19-36	IEC 60601-1-2:2014+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
19-50	IEC TS 60601-4-2:2024 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical system
5-129	IEC 62366-1:2015+A1:2020 Medical devices - Part 1: Application of usability engineering to medical devices
Not Recognized	IEC 80601-2-26:2019 Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
1-139	ISO 80601-2-61:2017 Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
2-258	ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
10-130	ANSI Z80.36:2021 Ophthalmic - Light Hazard Protection for Ophthalmic Instruments

Recognition Number	Description
Not recognized	ISO 15004-2:2007 Ophthalmic instruments - Fundamental requirements and test methods Part 2: Light hazard protection
12-249	IEC 62471:2006 Photobiological safety of lamps and lamp systems
Guidance	
/	“General Principles of Software Validation” Document issued on: January 11, 2002
/	“Content of Premarket Submissions for Device Software Functions” Document Issued on June 14, 2023.
/	“Multiple Function Device Products: Policy and Considerations”, Document issued on June 14, 2023.
/	Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, Document Issued on September 27, 2023.
/	“Postmarket Management of Cybersecurity in Medical Devices” Document Issued on December 28, 2016
/	“Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices” Document issued on September 6, 2017
/	“Off-The-Shelf Software Use in Medical Devices” Document Issued on September 27, 2023.
/	“Electromagnetic Compatibility (EMC) of Medical Devices” Document issued on June 6, 2022.
/	“Applying Human Factors and Usability Engineering to Medical Devices” Document issued on: February 3, 2016
/	Draft guidance “Content of Human Factors Information in Medical Device Marketing Submissions” December, 2022.

## 6. SUBSTANTIAL EQUIVALENCE DISCUSSION

The comparison of the EEG-1260A Neurofax to its predicate device (EEG-1200A Series Neurofax K080546), the JE-940A EEG Amplifier unit to its predicate device (JE-921A Electrode Junction Box K080546), and the LS-940A Photic Stimulator to its predicate device (Lifelines Photic Stimulator K101691) and the discussion of the key aspects are presented in the following sections.

### Discussion for Intended Use

In comparing the Intended Use between the EEG-1260A Neurofax and its predicate device, the Intended Use are the same.

In comparing the Intended Use between the JE-940A EEG Amplifier Unit and its predicate device, the Intended Use are the same.

In comparing the Intended Use between the LS-940A Photic Stimulator and its predicate device, the Intended Use for the predicate device and LS-940A Photic Stimulator are used as a light source for photic stimulation,

### **6.1 Indications for Use**

In comparing the Indications for Use between the EEG-1260A Neurofax and its predicate device, there were no changes in the Indications for Use.

In comparing the Indications for Use between the JE-940A EEG Amplifier Unit and its predicate device, the Indications for Use are the same.

In comparing the Indications for Use between the LS-940A Photic Stimulator and its predicate device, the Indications for Use were modified to include more details to better support the intended use of the LS-940A as a light source for photic stimulation to confirm the responsiveness of EEG to photic stimulation during EEG tests and to test visual evoked potentials. Based on the Intended Use, the predicate device and LS-940A Photic Stimulator are regulated under the same regulation number and FDA product code.

### **6.2 Discussion for Technological Characteristics**

The EEG-1260A Neurofax and its predicate device have the same technological characteristics.

The JE-940A EEG Amplifier Unit and its predicate device have the same technological characteristics.

The LS-940A Photic Stimulator and its predicate device have the same technological characteristics.

### **6.3 Discussion for Design Characteristics**

There are slight differences between the EEG-1260A Neurofax System and the predicate as referenced. The differences are based on design changes to accommodate new design improvement and to ensure compliance with current applicable standards. The changes have been evaluated to ensure there is no impact on the safety and effectiveness of the EEG-1260A Neurofax System.

There are slight differences between the JE-940A EEG Amplifier Unit and its predicate device. The differences are based on design changes to accommodate new design features and to ensure compliance with current applicable standards. The changes have been evaluated to ensure there is no impact on the safety and effectiveness of the JE-940A EEG Amplifier Unit.

There are slight differences between LS-940A Photic Stimulator and the predicate accessory device. The differences are based on design changes to accommodate the subject device's intended use and to ensure compliance with current applicable standards. The changes have been evaluated to ensure there is no impact on the safety and effectiveness of the LS-940A Photic Stimulator.

## 6.4 Discussion for Compatible Devices

The EEG-1260A Neurofax System and predicate device require the device to be connected to Nihon Kohden amplifiers. The subject device is available with the same amplifiers as with the predicate device. Currently, there are more Nihon Kohden amplifiers that have received 510(k) clearance since the predicate device has cleared by FDA, the differences do not impact the safety and effectiveness of the EEG-1260A Neurofax System when compared to the predicate device.

When compared to the predicate, the JE-940A EEG Amplifier Unit may require the use of a Mini Electrode Junction box (JE-944A). The predicate may require the Mini Electrode Junction box (JE-922A) to relay the signal. Both JE-922A and JE-944A connect to electrode leads attached to patients and relays EEG and other vital signals to EEG Amplifier Unit. Both JE-922A and JE-944A are compatible with EEG-1260A Neurofax System.

## 6.5 Discussion for Performance Specifications

The EEG-1260A Neurofax System has been compared and evaluated using the same performance methods and testing criteria as the predicate.

The JE-940A EEG Amplifier Unit has been compared and evaluated using the same performance methods and testing criteria as the predicate accessory device.

When compared to the predicate accessory device, the LS-940A Photic Stimulator has been evaluated to the most current versions of the Applicable Standards. Any new standard has been considered to ensure safety and efficacy of the subject device.

## 7. CONCLUSION

The results of the substantial equivalence assessment, taken together with non-clinical bench testing, electrical safety, and electromagnetic compatibility, software verification, and validation demonstrate that the EEG-1260A Neurofax, JE-940A EEG Amplifier Unit, and LS-940A Photic Stimulator do not raise concerns regarding their safety and effectiveness compared to their predicate device and operates in accordance with claimed indications for use. EEG-1260A Neurofax, JE-940A EEG Amplifier Unit, and LS-940A Photic Stimulator are substantially equivalent to the predicate devices.