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

August 21, 2015

Kvikna ehf
c/o Yolanda Smith
Smith Associates
1468 Harwell Ave
Crofton, MD 21114

Re: K143487
Trade/Device Name: Lifelines iEEG 2.0
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLT, GWQ
Dated: July 22, 2015
Received: July 23, 2014

Dear Ms. Smith:

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" (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 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,

Carlos L. Pena -S

Carlos 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)*
K143487

Device Name
Lifelines iEEG 2.0

Indications for Use *(Describe)*
The Lifelines iEEG is an EEG system that allows acquisition, display, archive, storage and analysis of physiological signals. The intended user of this product is a qualified medical practitioner trained in electroencephalography who will exercise professional judgment in using the information. The Lifelines iEEG system also includes the display of a quantitative EEG plots, power spectrum, which is intended to help the user to monitor and analyze the EEG. This device does not provide any diagnostic conclusion about the patient's condition to the user.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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

SPONSOR

Company Name:	Kvikna Medical ehf
Company Address	Stórhöfði 21 110 Reykjavik Iceland
Telephone:	+354 578 8400
Contact Person:	Gardar Thorvardsson
Summary Preparation Date:	November 14, 2014

DEVICE NAME

Trade Name:	Lifelines iEEG 2.0
Common/Usual Name:	EEG System
Classification Name:	Electroencephalograph
Regulation Number**:**	21 CFR 882.1400 GWQ,
Product Code:	GWQ, OLT
Device Class:	Class II

PREDICATE DEVICE

Company	***Product***	***510(k) #***
Natus Medical, Inc	DG Nervus	K964280

DEVICE DESCRIPTION

Lifelines iEEG is medical device used to acquire, display, archive, store and analyze EEG examinations. The EEG is presented in a conventional way and conventional signal processing is applied such as re-montaging and band pass filtering. The system is also capable of acquiring and presenting digital video synchronized to the EEG if this is available. Some advanced analysis methods are provided as an aid: FFT analysis and Artifact Removal. The system software is designed using service oriented architecture enabling the possibility of reviewing data over WAN without the use of additional remote desktop software solutions.

The components of Lifelines iEEG are:

- Lifelines iEEG software:
  - iEEG Centrum
  - iEEG Review
  - iEEG Acquisition
- Lifelines Trackit, Lifelines Ltd, 510(k)#K010460
- Lifelines Photic Stimulator, Lifelines Ltd, 510(k)# K101691
- Off the shelf PC and medical grade power supply
- Off the shelf IP Video Camera

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INDICATIONS FOR USE

The Lifelines iEEG is an EEG system that allows acquisition, display, archive, storage and analysis of physiological signals. The intended user of this product is a qualified medical practitioner trained in electroencephalography who will exercise professional judgment in using the information. The Lifelines iEEG system also includes the display of a quantitative EEG plots, power spectrum, which is intended to help the user to monitor and analyze the EEG. This device does not provide any diagnostic conclusion about the patient's condition to the user.

Caution: Federal law restricts this device to sale by or on the order of a physician licensed by the law of the State in which he practices to use or order the use of the device.""

COMPARISON OF PREDICATE PRODUCTS TECHNICAL CHARACTERISTICS

	Subject Device	Predicate Device	Similarities and Differences
Trade Name	Lifelines iEEG	DG Nervus (now NicoletOne)	
Company	Kvikna Medical ehf	Natus Medical, Inc.	
K Number		K964280	
Intended Use	The Lifelines iEEG is an EEG system that allows acquisition, display, archive, storage and analysis of physiological signals. The intended user of this product is a qualified medical practitioner trained in electroencephalography who will exercise professional judgment in using the information. The Lifelines iEEG system also includes the display of a quantitative EEG plots, power spectrum, which is intended to help the user to monitor and analyze the EEG. This device does not provide any diagnostic conclusion about the patient's condition to the user.	The Nervus DG is intended to be used as an Electroencephalograph: to acquire, display, store and archive electroencephalographic signals from the brain using a full montage array (i.e. 16 or more electrodes) and user specified locations.	The Lifelines iEEG system (Subject Device) and the DG Nervus have equivalent intended use.
Intended User	Qualified medical practitioner trained in Electroencephalography	Qualified medical practitioner trained in Electroencephalography	No difference.
Population age	All age groups	All age groups	No difference.
Use environment	Hospital, clinics, patients home	Hospital, clinic, patients home	No difference.
Regulation Number	21 CFR 882.1400	21 CFR 882.1400	No difference.
Product Code	GWQ, OLT	GWQ	Lifelines iEEG includes OLT product code as it offers quantitative EEG in the form of power spectrum and related parameters.
Device allows acquisition of physiological signals	Yes	Yes	No difference.

	Subject Device	Predicate Device	Similarities and Differences
Trade Name	Lifelines iEEG	DG Nervus (now NicoletOne)	
Device allows display, archive, review and analysis of physiological signals	Yes	Yes	No difference.
Identifies spikes	No	Yes	Lifelines iEEG does not offer automated spike detection
Identifies seizures	No	Yes	Lifelines iEEG does not offer automated seizure detection
Displays calculated EEG measures	Yes	Yes	No difference.
Calculated EEG measures displayed	Spectrum, Power Spectrum Density, band power, spectral edge, peak frequency	Spectrum, Spectrogram, band power, peak frequency, spectral edge	No difference. The algorithm used to calculate Spectrogram in DG Nervus and Power spectrum density in iEEG is the same.
Users can add/delete events	Yes	Yes	No difference.
Number of EEG channels	Software: up to 128 Hardware: up to 32	Up to 512	Lifelines system and Lifelines iEEG software system support up to 128 channels, the DG Nervus supports up to 512 channels.
Type of EEG recording supported	EDF, NicoletOne, Lifelines iEEG	EDF, NicoletOne	The Lifelines iEEG system and the Lifelines iEEG software system support the Lifelines iEEG (.ieeg) recording type which DG Nervus does not
Type of EEG analysis	Clinical, ambulatory, long term monitoring	Clinical, ambulatory, long term monitoring	No difference.
Photic activation of the EEG	Yes	Yes	No difference.
Differential input impedance	>20 Mohms	> 20MΩ	No difference.
Common mode input impedance	>100 Mohms	> 100MΩ	No difference.
Channel equivalent input noise	<3.5 µV pk–pk @ 0.16Hz to 70Hz	< 1.5µV pk-pk @ 0.16Hz to 70Hz	Slight difference.
Frequency band	0.16Hz to 70Hz (–6dB)	0.16–500Hz (-6dB) (± 10%)	Slight difference.
Low filter	0 Hz–5 Hz or off, in 11 predefined steps	0.16Hz–5Hz (± 10%), in 7 predefined steps or customizable up to 1000Hz or off	Slight difference.
High filter	10 Hz–100 Hz or off, in 9 predefined steps	15Hz–100Hz (± 5%), in 7 predefined steps or customizable up to 1000Hz or off	Slight difference.
Sampling rate	200, 256 Hz	1024, 512, 256 and 128 Hz,	Slight difference.

	Subject Device	Predicate Device	Similarities and Differences
Trade Name	Lifelines iEEG	DG Nervus (now NicoletOne)	
Wireless Communication between Amplifier and Computer	Yes	No	Wireless Communication between Amplifier and Computer is an added feature of the Lifelines iEEG system.
Video Camera Support	Yes	No	Video Camera Support is an added feature of the Lifelines iEEG system.

Discussion of Similarities and Differences

The Lifelines iEEG system is an update to the previously released Lifelines iEEG software system (K123665). The main difference is the inclusion of acquisition capabilities, which includes both new software features and hardware components.

A list of new/improved features associated with the acquisition capabilities can be found in the following table:

Feature	Feature description / Enhancement
Acquire Portable Operator View	The view available to the operator of an acquisition system.
Acquisition	Acquisition of EEG and other signals.
Amplifier Setup	The amplifier setup provides the user interface to configure the EEG amplifier used.
Exam for Acquisition	Prepare for acquiring a patient.
Exam Spaces	It is now possible to set an exam space for an acquisition system. Two acquisition systems cannot share an exam space. When an acquisition system connects to a main central data storage, an exam space shall be generated for it if it doesn't already exist.
Exam Types	It is now possible to associate an xps document (help page) with an exam type.
Help Pages	Help pages, containing contact information for techs, etc. shall be easy to customize by each customer.
Hyperventilation Timer	Patients are asked to hyperventilate as part of standard EEG protocol. The timer shows the operator for how long the patient has been hyperventilating and marks events for later reference.
Impedance Test	Impedance test is usually done in the beginning of an EEG test in order to check the quality of the electrode connections. This is also sometimes done while recording in order to check if any electrode needs to be fixed or re-applied.

Feature	Feature description / Enhancement
Patient Room View	During home monitoring or long-term monitoring within a hospital, it is beneficial that the patient (or the patient's parents) are able to see some information on the screen and even be able to communicate with the operator.
Photic Stimulation	The ability to control a photic stimulator from the system.
Synchronization	Synchronization of patient and exam data is now available when acquiring without network connection. Transfer of recorded data from the acquisition system to the main database.
Trackit Acquisition	Acquisition from the Trackit EEG amplifier
Video Acquisition	Digital video is acquired synchronized to the EEG.
Video Acquisition Configuration	Configuration of video cameras for video acquisition.

The hardware components provided with the system can be found in the following table:

Part	Quantity
PC computer (Lenovo ThinkPad T440)	1
Lifelines Trackit Mk3 EEG Amplifier	1
Lifelines LED Photic Stimulator	0 or 1
Power over Ethernet Switch (PoE) (Planet Desktop PoE Switch)	0 or 1
Medical Grade Power Supply for PC (TRUMPower 20V Medical and ITE Power Adapter)	1
Medical Grade Power Supply for PoE Switch (TRUMPower 48V Medical and ITE Power Adapter)	0 or 1
IP Video Camera (HIKVISION IR Cube Network Camera)	0, 1 or 2
USB 3.0 Ethernet Adapter (Lenovo ThinkPad USB 3.0 Ethernet Adapter)	1
Network Cat6 RJ45 0,5 m	0 or 1
Network Cat6 RJ45 3,0 m	0, 1 or 2
Splitter Power Cord (C14 to C13 splitter cord)	0 or 1
Power Cord	1

Other than the acquisition capabilities the Trend Analysis, Spectral Calculations and Save As… features are new to the system, other software functions are unchanged or changes are very minor. A list of new features and enhancements to existing features can be found in the following table:

Feature	Enhancement

Feature	Enhancement
Auditing	Audit trail is now recorded when an exam is exported.
Events	Duration events now display the elapsed time in 20 second intervals and the entire duration at the end.
Exam Types	The following exam types are now predefined in the system: *Video Ambulatory *Generic *NicOne
Labels	The EEG labels M1 and M2 are now predefined in the system. They have the same coordinates as A1 and A2 respectively.
Labels	The label type: *ECG Unipolar is now predefined in the system.
Labels	The non-EEG labels: *ECGL and ECGR of type ECG Unipolar and *ECG1 and ECG2 of type ECG Unipolar are now predefined in the system.
Montages	It is now possible to apply an exam's "Input" montage. The Input montage contains all recorded channels and unipolar channels derived to common reference.
Online Data Transfer	If a wireless network is selected to be used, the internet gateway is now switched to this connection automatically.
Report Generation	It is now possible to see all reports associated with exams belonging to the same visit in a single list.
Save As…	It is now possible to save a copy of an exam as a new exam in the system.
Spectral Calculations	It is now possible to calculate the spectrum of a block of EEG.
Spike and Seizure detection	When Persyst spike and seizure detection has been run on an exam, an event is now added at the beginning of the exam stating that the detection has been run and by which version of Persyst.
Task Processing	It is now possible to define tasks that run periodically with predefined interval between runs.
Trend Analysis	Mathematically transformed EEG is now displayed on a compressed timescale.
Version Control	The client software now displays the name and (new) address of the manufacturer, namely: “Kvikna ehf, Storhofdi 21, 110 Reykjavik, Iceland”

The Lifelines iEEG system and the DG Nervus system have equivalent intended use, the same intended user, population, age and regulation number. Also, the principles of operations between the devices are more or less the same, including the signal processing. But the systems do have a few minor differences. The DG Nervus system identifies spikes and seizures but the Lifelines iEEG system does not. The DG Nervus system supports up to 512 EEG channels while the Lifelines iEEG supports up to 128 (software, the hardware supports up to 32 channels). The Lifelines iEEG system supports the Lifelines iEEG (.ieeg) recording type. The Lifelines iEEG states the OLT product code that DG Nervus does not. However the quantitative EEG functions are equivalent such that this does not reflect a true difference of the products.

The principles of operation of the software are the same or very similar, including the signal processing i.e. the calculation of EEG montage, band-pass and notch filtering and the method used to plot the data to screen. The algorithm used to calculate Spectrogram in DG Nervus and Power spectrum density in iEEG is the same, in both cases the EEG is segmented into blocks and power spectrum calculated by Welch periodogram method. The results are also presented in the same way by color coding the power spectrum for each block of EEG and stacking the color coded blocks for the entire EEG recording. The major difference is that the Nervus DG system makes use of proprietary EEG amplifier and photic stimulator while the Lifelines iEEG system includes 3rd party medical device components for the same purpose.

The spike and seizure detection, provided by the DG Nervus, are nice-to-have features that are not essential to an EEG system. Therefore, the fact that the Lifelines iEEG system does not include them does not impact safety nor efficacy of the system. The same can be said about number of EEG channels supported.

NON-CLINICAL PERFORMANCE DATA

Software Verification and Validation.

Immunity Verification.

Third party testing for conformance with IEC 60601-1:2005 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

Third party testing for conformance with IEC 60601-1-2:2007 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

Checklist testing for IEC 62304:2006 – Medical Device Software – Software Life Cycle Processes

Checklist testing for IEC 62366:2007 - Medical Devices - Application Of Usability Engineering To Medical Devices

Third party testing for conformance with IEC 60601-2-26:2002 - Medical electrical equipment - Part 2-26: Particular requirements for the safety of electroencephalographs

CONCLUSION

Based upon the intended use, technological characteristics and safety and performance testing, it is the conclusion of Kvikna Medical ehf that the device consisting Lifelines iEEG system, an EEG system that allows acquisition, display, archive, storage and analysis of physiological signals, is as safe and effective as the predicate devices and raises no new issues of safety and effectiveness.