MAR 2 5 2013

510(k) Summary
807.92(c)

SPONSOR **807.92(a)(1)**

Company Name:	Kvikna ehf
Company Address	Vatnagardar 18 104 Reykjavik Iceland
Telephone:	+354 578 8400
Contact Person:	Gardar Thorvardsson

Summary Preparation Date: March 22, 2013

DEVICE NAME **807.92(a)(2)**

Trade Name:	Lifelines iEEG
Common/Usual Name:	EEG Software
Classification Name:	ELectroencephalograph
Regulation Number:	21 CFR 882.1400
Product Code:	OLT
Device Class:	Class II

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

K Number	Product	Company
K090019	Natus Neuroworks, Model 104196	Natus Medical, Inc.
K964280	DG Nervus	Natus Medical, Inc.
K021185	Nervus Monitor	Taugagreining hf

DEVICE DESCRIPTION **807.92(a)(4)**

Lifelines iEEG is software system used to manage and review EEG examinations. It works on data acquired by third party EEG equipment that is imported into the system. 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 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 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 two main components of Lifelines iEEG are iEEG Centrum and iEEG Review.

DEVICE INTENDED USE 807.92(a)(5)

The Lifelines iEEG is a software system that displays physiological signals. The intended user of this product is a qualified medical practitioner trained in Electroencephalography. This device is intended to be used by qualified medical practitioners who will exercise professional judgment in using the information.

- The Lifelines iEEG software allows display, archive, review and analysis of physiological signals.
- Lifelines iEEG also includes the display of a quantitative EEG plot, 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 (USA) law restricts this device to sale by or on the order of a physician.

COMPARISON OF TECHNICAL CHARACTERISTICS 807.92(a)(6)

	Subject Device	Predicate Device	Predicate Device	Predicate Device
Trade Name	Lifelines iEEG	Natus Neuroworks, Model 104196	DG Nervus (now NicoletOne)	Nervus Monitor
Company	Kvikna ehf	Natus Medical, Inc.	Natus Medical, Inc.	Taugagreining hf
Intended Use	The Lifelines iEEG is a software system that displays physiological signals.	The Neuroworks is EEG software that displays physiological signals	The Nervus DG is a medical device that records and displays physiological signals.	The Nervus Monitor is a medical device that records and displays physiological signals.
Intended User	qualified medical practitioner trained in Electroencephalography	qualified medical practitioner trained in Electroencephalography	qualified medical practitioner trained in Electroencephalography	qualified medical practitioner trained in Electroencephalography
Population age	All age groups	All age groups	All age groups	All age groups
Regulation Number	21 CFR 882.1400	21 CFR 882.1400	21 CFR 882.1400	21 CFR 882.1400
Product Code	OMB	OMB, OMA, OLT	GWQ	OLV
Software allows acquisition of physiological signals	no	yes	yes	yes
Software allows display, archive, review and analysis of physiological signals	yes	yes	yes	yes
Identifies spikes	No	yes	yes	yes
Identifies seizures	No	yes	yes	yes
Displays calculated EEG measures	Yes	yes	yes	yes
Calculated EEG measures	Spectrum, band power, spectral edge,	Spectrum, band power, spectral edge,	Spectrum, Spectrogram, band	Spectrum, Spectrogram, band

displayed	peak frequency.	peak frequency.	power, peak frequency, spectral edge	power, peak frequency, spectral edge
User adjustable seizure detection	no		no	No
Users can add/delete events	yes		yes	yes
Number of EEG channels	Up to 128		Up to 512	
Type of EEG recording supported	EDF, NicoletOne, Lifelines iEEG		NicoletOne, EDF	
Type of EEG analysis	Clinical, ambulatory		Clinical, ambulatory, long term monitoring	

PERFORMANCE TESTING

Software Verification and Validation

Safety Testing
IEC 60601-2-26, IEC 60601-1-4

CONCLUSION **807.92(b)(3)**

The predicate devices are EEG software products that allows for acquisition, review and archive of EEG and digital video picture of the patient as well as spike and seizure detection. They feature digital re-montaging and digital bandpass filters to aid the review process. They use an SQL database to keep track of exams and patient demographics and to control access to patient data.

The Lifelines iEEG has all the same functionality except for acquisition of EEG and the spike and seizure detection. The user must import eeg and video data acquired by other systems into the Lifelines iEEG system. Lifelines iEEG uses conventional, industry standard methods to re-montage and filter data in a similar way as the predicate devices. The data looks the same or very similar in all the devices. The only potential cause of the difference is the difference in the design of filters. This should not affect the safety or efficiency of the device provided that sound signal processing methods are applied.

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

March 25, 2013

Kvikna Ehf
c/o Yolanda Smith
Smith Associates
1468 Harwell Avenue
Crofton, MD 21114

Re: K123665
Trade/Device Name: Lifelines iEEG
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLT
Dated: February 25, 2012
Received: February 26, 2013

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 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,

Joyce M. Whang

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): K123665

Device Name: Lifelines iEEG

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang

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

510(k) Number K123665