K110967

JUN 30 2011

510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.87 and 807.92. Summary preparation date April 4, 2011 [21 CFR 807.92(a)(1)].

A. Applicant Name and Address [21 CFR 807.92(a)(1)]

Neuralynx Inc.

105 Commercial Drive

Bozeman, MT 59715-2217

Tel: (406) 585-4542

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B. Contact Information

Neuralynx Inc.

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Contact person: Michael Johnson M.D.

Email: mikejohnson@neuralynx.com

C. Device Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade Name: *Enterprise Electrophysiology System*

Device Common Name: Electroencephalograph

Classification Name: Electroencephalograph (per 21 CFR 882.1400)

Product Code: OMC

Panel: Neurology

Device Classification: Class II

D. Predicate Devices [21 CFR 807.92(a)(3)]

The *Enterprise Electrophysiology System* uses similar technology and has similar physical output characteristics as the following predicate device:

k060523 *NeuroPort* System manufactured by Cyberkinetics Neurotechnology Systems.

Parameters	*Neuralynx Enterprise Electrophysiology System*	*Cyberkinetics NeuroPort System*
510k number	K110967	K060523
Indications for Use	The intended use of the Neuralynx *Enterprise* Electrophysiology System is for temporary (<30 days) recording and monitoring of brain electrical activity.	The intended use of the Cybernetics Neurotechnology Systems, Inc. *NeuroPort System* is for temporary (<30 days) recording and monitoring of brain electrical activity.
Location of Use	Clinical, operating room, and epilepsy monitoring unit environments.	Clinical, operating room, and epilepsy monitoring unit environments.

Physical Characteristics	*Neuralynx Enterprise*	*Cyberkinetics NeuroPort System*
Amplifier	Interface Cabinet	Front End Amplifier / Digitizer
Signal processor	Interface Cabinet	Neural Signal Processor
Display	Monitoring Station PC	Display PC
Electrodes	*Neuralynx Enterprise*	*Cyberkinetics NeuroPort System*
Electrodes supplied by Manufacturer	No Uses AdTech (k053363) and PMT (k082474) electrodes	Yes Uses NeuroPort Electrode Array(k042384, k070272)
Anatomical Sites of Use	No direct patient contact	Manufactures electrodes which contact patient
System connects to electrodes	Yes	Yes
Function	*Neuralynx Enterprise*	*Cyberkinetics NeuroPort System*
Number of Channels	Up to 160 channels	Up to 128 channels
Sampling Resolution	24 bit A/D	16 bit A/D
Analog Bandwidth	DC to 8KHz	unknown
Sampling Frequency	32,556 samples per second per channel	30,000 samples per second per channel
Analog Input Range	+/- 132 millivolts 1 microvolt per bit at bit #18	8.1 mv to -8.1 mv
Input Noise Levels	8 microvolt peak to peak 1.3 microvolt RMS	14 microvolt peak to peak 3 microvolts RMS
Common mode rejection	100db	90 db
CMR Input Range	+/- 10v	+/- 3v
Number of references	1 per channel	1 per bank of 32 channels
Interface Cabinet to PC data communications connection	Fiber Optic Cable	Fiber Optic Cable
Electrical Classification	Class 1, continuous operation	Class 1, continuous operation
Degree of protection against electrical shock	Type BF	Type BF

E. Device Description [21 CFR 807.92(a)(4)]

The *Enterprise Electrophysiology System* is an electroencephalograph (EEG) device intended for recording and monitoring electrical brain activity. Functions include routine recording of brain activity, monitoring of brain activity, and retrieval and replay of recordings. The *Enterprise System* supports 160 channels of recording. The *Enterprise System* does not include electrodes. The system includes the Clinical Headstage, Interface Cabinet, and a Monitoring Station PC. The *Enterprise System* software supports acquisition and display.

F. Device Specifications [21 CFR 807.92(a)(6)]

The Neuralynx *Enterprise System* does not include the electrode arrays. These are supplied by AdTech (K053363) or PMT (K082474). The *Enterprise System* includes the headstage connection to the electrode arrays. The headstage connects to the Interface Cabinet which controls the acquisition of unprocessed data. The Interface Cabinet connects to the Monitoring Station PC by way of a fiberoptic Ethernet connection. The software in the Monitoring Station PC controls the display and processing of signal channels. Raw data channels are stored without manipulation.

G. Indications for Use [21 CFR 807.92(a)(5)]

The intended use of the Neuralynx *Enterprise Electrophysiology System* is for temporary (<30 days) recording and monitoring of brain electrical activity.

H. Performance Data [21 CFR 807.92(b)(2)]

Testing was conducted to verify that the *Enterprise System* met design specifications and was substantially equivalent to the predicate devices. Testing consisted of third party verification of adherence to IEC 60601-1, IEC 60601-1-2, IEC 606012-2-26. Software verification was also performed. No Clinical testing is required.

I. Conclusion [21 CFR 807.92(b)(3)]

Technologically, the *Enterprise System* was found to be substantially equivalent to the currently cleared k060523/k042626 *NeuroPort* manufactured by Cyberkinetics Neurotechnology Systems Inc. The indications for use are identical to the previously cleared device. The risks and benefits for the *Enterprise System* are argued to be comparable to the predicate devices. We believe that there are no new questions of safety or efficacy raised by the introduction of the *Enterprise System*. The nonclinical performance testing demonstrates that the *Enterprise System* is as safe, as effective, and performs at least as safely and effectively as the legally marketed device.

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

Neuralynx, Inc.
Michael Johnson M.D.
Clinical and Regulatory Manager
105 Commercial Drive
Bozeman, MT 59715

JUN 30 2011

Re: K110967
Trade/Device Name: Enterprise Electroencephalographic System
Regulation Number: 21 CFR 882.1400
Regulation Name: Reduced-Montage Standard Electroencephalograph
Regulatory Class: Class II
Product Code: OMC
Dated: April 4, 2011
Received: April 6, 2011

Dear Dr. Johnson

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,

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

Indications for Use

510(k) Number (if known): K110967

Device Name: *Enterprise Electrophysiology System*

Indications for Use:

The intended use of the Neuralynx *Enterprise Electrophysiology System* is for temporary (<30 days) recording and monitoring of brain electrical activity.

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)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K110967