

510(k) Summary

K092625

807.92(c)

JUN 29 2010

SPONSOR

807.92(a)(1)

Company Name: Wavestate, Inc.
Company Address: 333 Washington Blvd. #15
Marina del Ray, CA 90292
Telephone: 310-591-8844
Fax: 310-591-8191
Contact Person: Michael J. Bier Ph.D., President and CEO

Summary Preparation Date: June 29, 2010

DEVICE NAME

807.92(a)(2)

Trade Name: Wavestate Neuromonitor
Common/Usual Name: EEG
Classification Name: Electroencephalograph
Regulation Number: 882.1400
Product Code: ORT / GWQ
Device Class: II

PREDICATE DEVICE

807.92(a)(3)

Legally Marketed Equivalent Device

<i>Company</i>	<i>Product</i>	<i>510(k) #</i>
Taugagreining HF	Nervus Monitor	K021185
Viasys NeuroCare, Inc.	NicoletOne System V32	K061908
Lifelines Ltd.	Lifelines Trackit	K010460

DEVICE DESCRIPTION

807.92(a)(4)

Wavestate, Inc. has created a new application for the TrackIt-2, an FDA-approved ambulatory EEG hardware unit manufactured by Lifelines, Ltd (UK). Our proprietary software analyzes EEG data files recorded with the TrackIt-2. Data are displayed on an Xplore touch-screen tablet computer using Microsoft Windows XP.

Our application is used to quantify the inter-burst interval with 95% statistical confidence the duration of the interval within +/- 2 seconds.

The Trackit-2 system is FDA approved.

FDA-approved EEG electrodes will be bought separately by the end user.

DEVICE INTENDED USE**807.92(a)(5)**

The Wavestate Neuromonitor System is intended to collect, record, and store up to 24 channels of adult EEG data for up to 24 hours. The System also can perform a post review of adult EEG data and identify burst suppression pattern in the stored EEG. The device displays the mean interburst interval reviewed up to that time point and the probability that the displayed value is within +/- 2 seconds of the mean of the interburst intervals for the entire dataset for that patient. The Wavestate Neuromonitor System does not provide any diagnostic conclusion about the patient's condition to the user. The Wavestate Neuromonitor is to be used under the guidance and interpretation of a licensed medical practitioner.

Caution: (USA law) Restricts this device to sale by or on the order of a physician.

Predicate Product Comparison

**NONCLINICAL AND CLINICAL TEST
SAFETY and EFFECTIVENESS****807.92(b)**

Testing of the Wavestate Neuromonitor was performed. Testing included:

1. Software verification and validation
2. Electrical and EMC safety compliance to:
 - IEC 60601-1
 - IEC 60601-1-2
 - IEC 60601-2-26

Software Verification and Validation Summary**V&V SUMMARY**

The validation testing demonstrates how each feature of the burst suppression algorithm is accurately implemented. The algorithm consists of five features: (1) burst detection, (2) channel logic, (3) suppression duration, (4) interburst interval, and (5) statistical confidence.

First, the accuracy of burst detection is tested in a single EEG channel. 40-ms-duration spikes of varying amplitude are inserted into digitized EEG files consisting of background activity (< 5 microvolts). The results demonstrate the accuracy of detection as only spikes of 10 microvolts or higher are identified.

Second, the accuracy of burst detection is tested in multiple channels. Test results demonstrate accurate detection of 10.5 microvolt spikes identified independently and simultaneously in each EEG of the 19 channels tested.

Third, the accuracy of EEG suppression detection is tested. EEG suppression is defined as 500 ms of activity below 10 microvolts. Spikes of 10.5 microvolt amplitude are inserted, at increasing interval length, into an EEG file consisting of baseline background

activity. Test results demonstrate detection of suppression only when spikes are separated by 500 ms or longer.

Fourth, the accuracy of calculating and displaying the statistical mean of the interburst interval is tested. Spikes of 10.5 microvolt amplitude are inserted at increasing intervals into an EEG file consisting of background activity. Test results demonstrate accurate calculation and display of the mean interburst interval as an integer.

Fifth, the accuracy of the statistical confidence computation is tested. A series of interburst intervals are constructed with 10.5 microvolt spikes. The series converge on a 10-second mean with variance decreasing initially, followed by increasing variance. This results in an initial mean of low statistical confidence and with increasing stability interburst interval stability the confidence interval reaches 95%. Test results demonstrate that the mean interburst interval is displayed once statistical confidence attains 95% and is not displayed when confidence is below 95%.

COMPARISON OF TECHNICAL CHARACTERISTICS
807.92(a)(6)

Caution: (USA law) Restricts this device to sale by or on the order of a physician.

Parameters	New Device	Predicate Device	Predicate Device	Predicate Device
Proprietary Name	Neuromonitor	Trakit	Nicolet OneViasys	Nervus
Manufacturer	Wavestate Inc.	Lifelines	NeuroCarc, Inc	Taugagreining Hf
Intended User	Licensed medical professional	Licensed medical professional	Licensed medical professional	Licensed medical professional
Target population	Adult	Adult	Adult	Adult and pediatric patients
No of EEG channels	24 monopolar touchproof inputs	24 monopolar touchproof inputs	16 to 32 monopolar touchproof inputs	16 to 32 monopolar touchproof inputs
Max. common mode input voltage	2V pk-pk	2V pk-pk	-	2V pk-pk
Input bias current	<25nA @25° C	<25nA @25° C	-	<20nA @25° C
Differential Input Impedance	>20 Mohms	>20 Mohms	-	>20 Mohms
Common mode input impedance	>100 Mohms	>100 Mohms	>100 Mohms	>100 Mohms
Common mode rejection ratio	>110d @ 0.16Hz to 70Hz w/ active ground connected	>110d @ 0.16Hz to 70Hz w/ active ground connected	>110d @ 50/60 Hz	>110d @ 0.16Hz to 70Hz w/ active ground connected
Channel hardware gain	1000 ± 2%	1000 ± 2%	-	500
Max. differential AC input before clipping	10 mV pk-pk	10 mV pk-pk	-	10 mV pk-pk
DC Input tolerance	±500mV	±500mV	±350mV	
Burst Suppression	yes	no	yes	yes

Predicate Product Comparison



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Wavestate, Inc.
c/o Ned Devine
Underwriters Laboratories, Inc.
333 Pfingsten Road
Northbrook, IL 60062

JUN 29 2010

Re: K092625

Trade/Device Name: Wavestate Neuromonitor
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: ORT, GWQ
Dated: April 28, 2010
Received: April 30, 2010

Dear Mr. Devine:

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" (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 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

Enclosure

Indications for Use

510(k) Number (if known): K092625

Device Name: Wavestate Neuromonitor

Indications for Use:

The Wavestate Neuromonitor System is intended to collect, record, and store up to 24 channels of adult EEG data for up to 24 hours. The System also can perform a post review of adult EEG data and identify burst suppression pattern in the stored EEG. The device displays the mean interburst interval reviewed up to that time point and the probability that the displayed value is within +/- 2 seconds of the mean of the interburst intervals for the entire dataset for that patient. The Wavestate Neuromonitor System does not provide any diagnostic conclusion about the patient's condition to the user. The Wavestate Neuromonitor is to be used under the guidance and interpretation of a licensed medical practitioner.

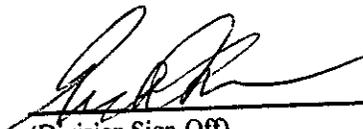
Caution: (USA law) Restricts this device to sale by or on the order of a physician.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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