FEB - 6 2004

510(K) SUMMARY

Date: February 4, 2004

Company: Physiometrix, Inc.
Five Billerica Park
101 Billerica Avenue
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Contact: Dawn E. Frazer
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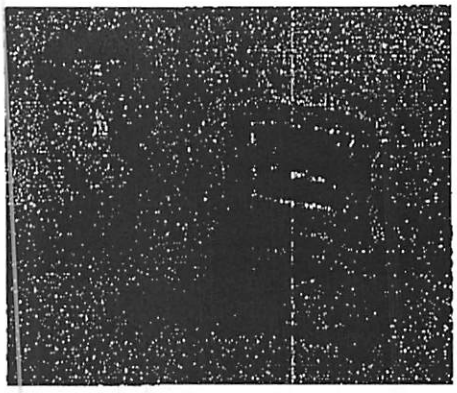
Subject Device: Sedline with Frontal PSI

Classification: Class II, 21 CFR Part 882.1400, Electroencephalograph

Intended Use: The Sedline System is indicated for use in the operating room (OR), intensive care unit (ICU), and clinical research laboratory. It is intended to monitor the state of the brain by real-time data acquisition and processing of EEG signals. The system includes the Patient State Index (PSI), a proprietary computed EEG variable that is related to the effect of anesthetic agents.

Description: Sedline is an EEG monitor designed for use in the OR, ICU, EEG laboratory and for clinical research. It provides the ability to acquire and display real-time EEG waveforms, process the real time EEG data using digital signal processing techniques, display the processed EEG data in several different formats, and archive the real-time or processed EEG data for future review.

The Sedline System consists of five components, the monitor, PSI algorithm, amplifier, patient cable and PSArray2 EEG Electrode Set. The device performs automatic self tests upon power up to ensure that the monitor and its components are functioning properly.



Monitor

The monitor provides signal processing and display capabilities for the 4 channels of real-time EEG data acquired from the preamplifier.

The monitor dimensions are 9" W x 8" H x 6" D. The color display area is 3.8" H x 5.2" W. In addition to the display area, the front panel is configured with a number of buttons to allow for configuration of the display and data acquisition settings. The monitor includes a base and a clamp that can be used to secure the unit on a flat surface or on a pole (respectively).

The processor is a PC-based CPU that processes the EEG data, calculates the processed parameters and displays the real-time EEG data and processed data. Processed parameters include Electromyograph (EMG), Artifact (ART), Suppression Ratio (SR), and the Patient State Index (PSI).

The monitor is powered through either standard wall outlet through a power cable or by the internal back-up battery power.

PSI Algorithm

The PSI algorithm is used to convert EEG acquired from four active (F7, F8, Fp1 and Fp2), ground (FpZ) and reference (AFZ) into a proprietary index, the PSI. The PSI is an EEG variable that is related to the effect of anesthetic agents.

Patient Module

The patient module is an electrically isolated, low noise, high gain, analog to digital signal converter that can process up to 4 channels of real-time data.

The preamplifier dimensions are 4.25" W x 1.75" D x 5.5" H. The patient module includes a clamp that can be used to secure the unit. The clamp can accommodate a pole, bed rail or bed sheet with a thickness of up to 1". The preamplifier is connected to the patient and monitor through flexible, shielded cabling.

Patient Cable

The patient cable is used to connect the patient module to the PSArray^2. The cable is 6 feet in length and terminated on one end with a 12 pin round connector design to mate with the patient module, and on the other end with a connector designed to mate with the PSArray^2.

PSArray^2

The PSArray2 is an EEG Electrode Set designed for use with the Sedline System. It is comprised of six EEG electrodes that are located in a flexible substrate.

Note that this 510(k) does not encompass the PSArray2. This device is the subject of an already cleared pre-market notification, K020670.

Predicate Device: PSA4000 EEG Monitor with Frontal PSI (K020671)

Similarities: The subject device is similar to the predicate device in the following way(s):

a. Both systems are EEG monitors.

b. Both systems provide a variety of processed parameters, EMG, SR, ART and PSI.

c. Both systems include the PSI, a proprietary computed EEG variable that is related to the affects of anesthetics.

d. Both conduct self tests at start up to assure that the device is operating.

e. Both systems use the same EEG Electrode Set, PSArray^2.

Differences: The subject device is different from the predicate device in the following way(s):

a. Different hardware as required to reduce size and weight of the monitor.

b. EMG trend display optional on Trend View.

c. Added DSA View

Test Results: The following tests have been conducted in order to verify and validate the device: software, mechanical and electrical validation testing and EMC testing.

The PSA4000 has been testing in accordance with the following standards.

- UL 2601
- CSA 22.2 No. 601-1
- IEC 601-1
- IEC 601-2-26
- FDA Reviewer Guidance for Premarket Notification Submissions, Section 7, Electromagnetic Compatibility dated November 1993.

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

Physiometrix
c/o Ms. Dawn E. Frazer
Vice President, Regulatory Affairs and Quality Assurance
Five Billerica Park
101 Billerica Avenue
N. Billerica, Massachusetts 01862

APR - 9 2012

Re: K033999
Trade/Device Name: Sedline with Frontal PSI
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLW, OMC, ORT, OLT
Dated (Date on orig SE ltr): December 23, 2003
Received (Date on orig SE ltr): January 8, 2004

Dear Ms. Frazer:

This letter corrects our substantially equivalent letter of February 6, 2004.

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,

for Kesia Alexander

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 STATEMENT

510(k) Number (*if known*)	K033999
Device Name	Sedline with Frontal PSI
Indications For Use	The Sedline System is indicated for use in the operating room (OR), intensive care unit (ICU), and clinical research laboratory. It is intended to monitor the state of the brain by real-time data acquisition and processing of EEG signals. The system includes the Patient State Index (PSI), a proprietary computed EEG variable that is related to the effect of anesthetic agents.

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K033999