K963644

OCT -8 1996

VI 510(k) Summary

Description

The Aspect Medical Systems, Inc. EEG Monitors, Models A-1000 and A-1050 with the processed parameter BIS, (hereafter referred to as the Aspect EEG Monitors with BIS) are microprocessor-based, up to 4 channel EEG monitors designed for use in the OR, ICU and for clinical research.

They acquire and display real-time EEG waveforms, as well as process the real time EEG data using digital signal processing techniques including the Fast Fourier Transform technique, and display the processed EEG data in several different formats. The purpose of processing the EEG waveform data is to extract characteristic features from the complex signal in order to provide easier pattern recognition of changes over time during the recording.

The system configuration includes a monitor, digital signal converter (DSC), optional printer, cables and electrodes.

The EEG Monitors with BIS conform to UL 544, CSA 22.2 no. 125 Risk Class 3, IEC 601-1. They also meet electromagnetic interference specifications outlined in IEC 801-2,3,4,5.

The Aspect EEG Monitors with BIS consist of two main components:

1) Monitor
2) Digital Signal Converter (DSC) - 4 channel maximum

A-1000 - 2,4 channel DSC
A-1050 - up to 2 channel DSC

Monitors

The monitors are microprocessor-based, and provide signal processing and display capabilities, displaying up to 4 channels of real time (i.e. "raw") EEG data as well as computing and displaying processed EEG parameters (examples of some processed parameters are listed below). They also display trend plots of processed EEG parameters in real time.

The front panel is configured with a large display screen, an index display board composed of a numeric index display and an alphanumeric index label display. There are a number of soft and hard keys, such as Set-up, Print, Alarm Limits, Trend, EEG, CSA+, DSA+, Review and Event.

The monitors contain the processors for processing the EEG data, calculating the variables and displaying the waveforms and variables.

The monitors consists of a PC-based CPU, an IPU and an FPU. The latter two are Digital Signal Processing subsystems for EEG processing.

DSCs

The Digital Signal Converters (DSCs) are electrically isolated, low noise, high gain amplifiers that also filter and digitize up to four (4) channels of EEG waveform data in either a bipolar or referential montage.

An overcurrent detector circuit monitors current to the DSCs. If the current exceeds the expected value, the power is shut off to the DSCs by the hardware, and the IPU is notified.

The DSCs are connected to the monitor by a flexible monitor interface cable.

Processed Parameters

There are a number of processed parameters which include the following:

Compressed Spectral Array (CSA), Density Spectral Array (DSA), Suppression Ratio(SR), Spectral Edge Frequency (SEF), Signal Quality Index (SQI) and the Bispectral Index (BIS).

Indications for Use

The Aspect EEG Monitors with BIS are intended to monitor the state of the brain by data acquisition of EEG signals in the intensive care unit, operating room and for clinical research.

The Bispectral Index (BIS), a processed EEG variable, may be used as an aid in monitoring the effects of certain anesthetic agents.

Reference:

Glass P, Payne F, Rosow C, Sebel P, Manberg P. Bispectral Index (BIS) Monitoring Allows Faster Emergence and Improved Recovery From Propofol/Alfentanil/N2O Anesthesia. In preparation for Anesthesiology.

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Summary

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

Ms. M. Christine Morgida
Manager, Regulatory Affairs
Aspect Medical Systems, Inc.
2 Vision Drive
Natick, Massachusetts 01760-2059

APR - 9 2012

Re: K963644
Trade/Device Name: EEG Monitor, Models A-1000™ and A-1050™
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLW, OMC, ORT, OLT
Dated (Date on orig SE ltr): September 11, 1996
Received (Date on orig SE ltr): September 12, 1996

Dear Ms. M. Morgida:

This letter corrects our substantially equivalent letter of October 8, 1996.

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,

Kesia Alexander

for

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

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III INDICATIONS FOR USE

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Richard N. Phillips

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K963644