FEB 6 1998

K974496

II 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

510(k) SUMMARY **Date Prepared: November 26, 1997**

Company Name and Address

Aspect Medical Systems, Inc.
2 Vision Drive
Natick, MA 01760-2059

Contact People: Christine Morgida
Manager, Regulatory Affairs
Paul J. Manberg, PhD
Vice President, Clinical and Regulatory Affairs

Device Name

Proprietary Name: A-2000™ EEG Monitor with BIS. Common Name: EEG Monitor

Classification

Electroencephalograph (EEG) monitors have been classified by the Neurological Devices Panel as Class II devices (21 CFR 882.1400)

Predicate Device

Aspect Medical Systems EEG Monitor, Model A-1050 with BIS ™.
This 510(k), #K963644, received FDA clearance October 8, 1996.

Device Description

The Aspect A-2000 Monitor dimensions are 7 inches wide x 6.8 inches high x 4 inches deep. The active display area is 3.4 inches high x 4.5 inches wide, and displays Raw EEG waveforms, Density Modulated Spectral Array (DSA) (includes spectral edge frequency), Trend plots of processed EEG parameters in real time, Current BIS number, Signal quality and EMG indicators, and Suppression Ratio.

The Aspect A-2000 Monitor performs automatic self tests upon power up to ensure that the monitor and its components are functioning properly. A quick test of the DSC-2 is conducted upon first detection of the DSC-2.

In addition, comprehensive self tests can be initiated manually from the service menu. Results are reported on the display, and printed automatically if a printer is connected.

Digital Signal Converter (DSC-2)

The DSC-2 is used in the A-2000 system, and is identical to the digital signal converter used with the A-1050 system (510(k) #K952347, FDA clearance daie 1/16/96). It is an electrically isolated, low noise, high gain amplifier.

Its dimensions are: 2.50 x 3.75 x 1.00", and its weight is 4.5 ounces.

Printer

A two inch thermal strip printer is optional. When printing is initiated, an 8-10 second real time EEG strip is printed. When the monitor is displaying a trend, the printer outputs a horizontal trend plot of the entire case at the same scale as the main display.

Intended Use

The Aspect A-2000 EEG monitor with BIS is 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 BIS, a processed EEG variable, may be used as an aid in monitoring the effects of certain anesthetic agents.

Gan TJ, Glass PS, Windsor A, Payne F, Rosow C, Sebel P, Manberg P. **Bispectral Index (BIS) Monitoring Allows Faster Emergence and Improved Recovery From Propofol, Alfentanil and Nitrous Oxide Anesthesia. Anesthesiology** October 1997; (4) 87: 808-15.

Summary of Technological Characteristics Compared to Predicate Device

Similarities

Both devices are EEG machines that monitor the state of the brain by data acquisition of EEG of the anesthetized or sedated patient in the intensive care unit, operating room and for clinical research. Also, both are indicated for use as an aid in monitoring the effects of certain anesthetic agents by use of the processed parameter BIS.

The A-2000 and A-1050 Monitors with BIS have the same basic functions. The hardware systems are similar, the A-2000 Monitor having more highly integrated components. They have similar hardware and software designs, signal flow, self-test capabilities (automatic and manual), alarms, and identical Digital Signal Converters (DSC-2).

The A-2000 and A-1050 alarm capabilities include:

System Error Message Alarms for patient condition (i.e. EEG Isoelectric), lead connection (i.e. DSC Disconnected) and equipment messages (i.e. Software Errors). Both the A-1050 and A-2000 Monitors have written messages. Both have audible alarms associated with error messages.

Numeric Display Limit Alarms for the primary trend. Both the A-1050 and A-2000 Monitors have 3 ascending tones when the high limit is reached, and three descending tones when the low limit is reached.

A description of the System Error Message Alarms can be found in Section VII of the Operator's Manual. A description of the Numeric Display Limit Alarms can be found in Section II of the Operator's Manual.

- Printer support - Both the A-1050 and A-2000 Monitors have printer support capabilities.
- Self tests (automatic and manual) - Both monitors have automatic testing upon start up. Both monitors have manual testing of the DSC-2, as well as the hardware filter performance.
- DSC-2 (digital signal converter) - The A-2000 Monitor DSC-2 is identical to the A-1050 Monitor DSC-2 (other than a color change to the case).
- Trend BIS, SR, SQI, EMG - Both the A-1050 and A-2000 Monitors can trend all 4 of the above processed EEG variables. Both prominently display the primary trend in the graphic display.
- Data sampling rate (16,384 samples per second) - Identical

Minor Differences

There are 3 minor differences that occur in the following areas:

- Processed Parameters

CSA and DSA

The Aspect A-2000 Monitor has processed EEG displayed as DSA (Density Spectral Array) whereas the Aspect A-1050 Monitor with BIS graphically displays processed EEG as CSA and DSA. Both are graphic representations of the same thing, i.e. power spectra.

Median Frequency

The Aspect A-2000 Monitor does not have median frequency because this parameter is not used widely by anesthesiologists. Median frequency is defined as the frequency at which 50% of the total power lies to either side of it.

- Alarms

System Error Message Alarms
Both the A-2000 and the predicate device have written messages for 3 categories of errors (i.e. patient condition, lead connection and equipment messages). The differences are that the written messages may differ slightly (i.e. "DSC Power Regulation Fault" in the A-1050 with BIS will read "DSC Power Regulation" in the A-2000 Monitor). Also, with regard to the audible alarm, the Aspect A-1050 Monitor with BIS has a single tone alarm, whereas the A-2000 Monitor has a two tone alarm.

Numeric Display Limit Alarms
In both the Aspect A-2000 and A-1050 Monitors, this alarm occurs for those variables that are primary trended. For the A-2000 Monitor, these high and low limit alarms occur for the BIS. In the predicate device, the auxiliary alarms, i.e. EMG, Suppression Ratio and Signal Quality can be primary trended in addition to the BIS.

The following tests have been conducted: software, environmental, mechanical and electrical validation testing, as well as EMC testing. The Reviewer Guidance for Premarket Notification Submissions (1993) was followed (other than packaged product storage test - Appendix A, section (i) (6) (ii); this test will be completed once the package is finalized) and all test results are acceptable. Also, a hazard analysis was completed, and this document indicates Aspect has made diligent efforts to identify all the potential hazards that could be anticipated, and have found ways to mitigate them by various hardware and software designs, including labeling.

Aspect Medical Systems believes the A-2000 EEG Monitor with BIS is substantially equivalent to the Aspect A-1050 EEG Monitor with BIS, and is safe for its intended use.

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, MA 01760-2059

APR - 9 2012

Re: K974496
Trade/Device Name: Aspect Medical System A-2000 EEG Monitor with BIS
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLW, OMC, ORT, OLT
Dated (Date on orig SE ltr): November 26, 1997
Received (Date on orig SE ltr): November 28, 1997

Dear Ms. Morgida:

This letter corrects our substantially equivalent letter of February 6, 1998.

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

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510(k) NUMBER (IF KNOWN): K974496

DEVICE NAME: Aspect Medical Systems EEG Monitor with BIS, Model A-2

INDICATIONS FOR USE:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. Susan Runner (Reviewer)
(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K974496

Prescription Use X OR Over-The-Counter-Use____
(Per 21 CFR 801.109) (Optional Format 1-2-96)