K031694

October 10, 2003

VII 510(k) SUMMARY **Date prepared: 10//09/03**

Company Name and Address

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Newton, MA 02464

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Device Name

Proprietary Name: A-2000™ EEG Monitor with BIS

Common Name: EEG Monitor

Predicate Devices

Aspect Medical Systems EEG Monitor with BIS, Model A-2000
510(k) #K011534 and GE Medical Systems BIS Module 510(k) #K012466.

Description

The Aspect Medical Systems, Inc. A-2000 EEG BIS Monitor (hereafter referred to as the BIS Monitor) is an easy to use, microprocessor- based, 2 channel maximum EEG monitoring system. It is used to monitor the state of the brain by data acquisition of EEG. The BIS, a processed EEG variable, may be used as an aid in monitoring the effects of certain anesthetic agents.

There are no changes to the Monitor.

Indications for Use

The Aspect A-2000 EEG Monitor with BIS is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. The BIS Monitor is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals.

The BIS may be used as an aid in monitoring the effects of certain anesthetic agents. Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.

Brief Description of Clinical Tests

The B-Aware study was a prospective, randomized double blinded multi-center study to determine if the BIS technology reduces the incidence of awareness. 1227 were assigned to BIS monitoring, and 1228 to routine care (no BIS was used). Results of this study (n= 2503) are that BIS guided anesthesia significantly reduced the incidence of awareness by 82%.

The Safe-II was a prospective cohort study undertaken to determine if BIS monitoring would result in a reduction of awareness. This study compared the patients having had BIS monitoring (n=5057) with a historical group (n=7801) that had no BIS monitoring. Results are that use of BIS significantly reduced the incidence of awareness by78%.

The Kaplan study showed the risk of awareness and recall was reduced by 78% during sedation in the ICU setting.

The AIM (Awareness Incidence and Monitoring) study was a prospective, observational, cohort, multi-center study conducted in 7 hospitals in the US. This study was undertaken to determine the current incidence of intra-operative awareness in the US. Results of this study (n=19576) are that 1-2 cases of awareness per 1000 occur in the US, and this is similar to other non-US findings (i.e. Australia and Sweden).

The fact is that there are 20 million cases of anesthesia every year in the US, and there are 20,000 – 40,000 cases of awareness per year. Study results show that this number can be reduced by approximately 80% with the use of BIS monitoring, and can thus offer clinically meaningful benefit. A reduction in awareness provides a public health benefit, in that BIS technology can now provide anesthesiologists with a way to reduce this often debilitating, yet preventable medical error.

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

Aspect Medical Systems, Inc.
c/o Ms. Christine Vozella
Regulatory Affairs
1775 Rockies Court
Lafayette, Colorado 80026

APR - 9 2012

Re: K031694
Trade/Device Name: EEG Monitor with BIS Model A2000
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLW, ORT, OMC, OLT
Dated (Date on orig SE ltr): May 30, 2003
Received (Date on orig SE ltr): June 3, 2003

Dear Ms. Vozella:

This letter corrects our substantially equivalent letter of October 10, 2003.

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

510(k) Number (if known): K031694

Device Name: A-2000 EEG Monitor with BIS

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)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number 031694