K062613

Page 1 of 2

SECTION 6

SPECIAL 510(k) SUMMARY
Date Prepared: August 31, 2006
Revised June 11, 2007

JUN 18 2007

Company Name and Address

Aspect Medical Systems, Inc.
One Upland Rd.
Norwood, MA 02062

Contact Person: Vikram Verma
Manager, Regulatory Affairs/Quality Assurance
Telephone (direct dial): (617) 559-7134
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Device Name

Proprietary Name: Aspect Medical Systems BIS EEG Monitor, VIEW

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 A-3000 EEG Monitor with BIS (K052362)

Device Description

The BIS EEG Monitor, VIEW, is an EEG Monitor that displays EEG, as well as reports and graphs the BIS value by acquiring two channels maximum of EEG from sensors attached to the patient's head, and performing the computations necessary to produce the Bispectral Index (BIS). The BIS is then numerically displayed for the clinician's use.

It also displays other parameters such as SQI (signal quality) and EMG.

Indications for use

The BIS EEG Monitor, VIEW, 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; and its usage with certain anesthetic agents may be associated with a reduction in primary anesthetic use and a reduction in emergence and recovery time.

Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of incidence of awareness with recall in adults during general anesthesia and sedation.

Summary of Technological Characteristics Compared to Predicate Device

The BIS VIEW Monitor has the same intended use and fundamental scientific technology as the predicate device. It has a lesser number of features as compared to the predicate device, such as no secondary data trending, soft keys in place of touch screen, a smaller screen, no trend review screen and a different housing color as compared to the predicate device.

Summary of Testing

The following tests/analyses have been completed:

- Software Validation
- Hazard Analysis and Risk Assessment

Results indicate the device meets its performance specifications and validation test requirements, and is safe for its intended use.

Conclusion:

Based on the above, Aspect Medical Systems believes the VIEW Monitor is substantially equivalent to the predicate device, and is safe and effective 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

Aspect Medical Systems Inc.
c/o Mr. Vikram Verma
Manager, RA/QA
One Upland Road
Norwood, Massachusetts 02062

APR - 9 2012

Re: K062613
Trade/Device Name: BIS EEG Monitor View
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLW, OMC, ORT
Dated (Date on orig SE ltr): May 10, 2007
Received (Date on orig SE ltr): May 14, 2007

Dear Mr. Verma:

This letter corrects our substantially equivalent letter of June 18, 2007.

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 (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.

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,

Keysia 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

Indications for Use

510(k) Number (if known): K062613

Device Name: BIS EEG Monitor, VIEW

Indications for Use: 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.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

(Posted November 13, 2003)

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

510(k) Number K062613