K011834

JUL 1 0 2001

510(k) SUMMARY **Date Prepared: June 11, 2001**

Company Name and Address

Aspect Medical Systems, Inc.
141 Needham St.
Newton, MA 02464

Contact Person: Christine M. Vozella
Director, Regulatory Affairs/Quality Assurance

Device Name

Proprietary Name: BIS Engine (PCB component in an EEG Monitor)
Common Name: EEG Monitor

Classification

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

Predicate Device

BIS Engine	K002837, FDA cleared September 19, 2000
A-1000 EEG Monitor with 4 channel amplifier (DSC-4)	K923043A, FDA cleared December 3, 1992

Device Description

The Aspect Medical Systems, Inc. BIS Engine - 4 channel support provides the means for incorporating Aspect's proprietary BIS technology into OEM (original equipment manufacturer's, i.e. our business partner's) finished devices. It is a small printed circuit board (PCB) that can either reside inside the OEM finished device or is re-designed for smaller size and packaged in a housing that will connect to the OEM finished device.

The fundamental scientific technology has not changed. The BIS technology remains the same. The BIS Engine - 4 channel support (subject of this 510(k)) has the same basic function, and same operating principal as the Predicate Device.

Only the software is changing. More specifically, the only difference is that the BIS Engine (subject of this 510(k)) can process up to 4 channels of EEG, compared to the Predicate Device, which can process up to 2 channels of EEG. The BIS processed parameter will only be calculated when in 2 channel maximum mode.

Intended Use

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.

Summary of Technological Characteristics Compared to Predicate Device

The BIS Engine - up to 4 channel support is substantially equivalent to the Predicate device (BIS Engine - up to 2 channel support).

Similarities

The fundamental technology has not changed. The indications for use are the same. The BIS technology remains the same. The BIS algorithm is the same. The BIS Engine has the same parameters, same operating principle, and same signal processing design. The hardware design is the same. The electrical and mechanical designs are the same.

Minor Differences

Only the software is changing. More specifically, the only difference is that the BIS Engine (subject of this 510(k)) can process a maximum of 4 channels of EEG, compared to the Predicate Device, which can process a maximum of 2 channels of EEG. The BIS processed parameter will only be calculated when in 2 channel maximum mode.

The following analysis and validation was performed:

1) Risk analysis
2) Software validation

Results of risk analysis: There are no additional hazards introduced by the BIS Engine - 4 channel that are severe enough to warrant tracking on the risk management record.

Results of validation: The applicable testing was completed (the modified BIS Engine will be a component to a finished device owned by our business partners, and as such, there are no patient or user safety concerns due to the BIS Engine in and of itself).

Results show all tests are acceptable.

The BIS Engine - 4 channel support is substantially equivalent to the Predicate Device.

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. Christine M. Vozella
Director, Regulatory Affairs/Quality Assurance
Aspect Medical Systems, Inc.
141 Needham Street
Newton, Massachusetts 02464

APR - 9 2012

Re: K011834
Trade/Device Name: BIS Engine
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLW, OMC, ORT
Dated (Date on orig SE ltr): June 11, 2001
Received (Date on orig SE ltr): June 12, 2001

Dear Ms. Vozella:

This letter corrects our substantially equivalent letter of July 10, 2001.

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

Indications for Use Statement

510(k) Number (if known) K011834

Device Name Aspect Medical Systems, Inc. BIS Engine (4 channel support)

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)

for Mark N. Melkerson

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

510(k) Number K011834

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)