FEB 2 5 2004

K040183

510(k) SUMMARY **Date Prepared:** January 14, 2004

Company Name and Address

Aspect Medical Systems, Inc.
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Device Name

Proprietary Name: BISx
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

Aspect Medical Systems A-2000 (XP) EEG Monitor with BIS System
This 510(k), #K030267, received FDA clearance January 13, 2004

Device Description

The BISx is a component that processes up to two channels of EEG and computes the Bispectral (BIS) Index and other EEG parameters (same as predicate device), uniting the functionality of the Digital Signal Converter (DSC-XP) and the BIS algorithm into a single enclosure. The BISx mates on one side with Aspect's BIS sensors (up to 2 channel, all currently marketed). On the other side, the BISx attaches to OEM (other equipment manufacturers) patient monitoring systems, allowing them to display Aspect's proprietary BIS Index on their integrated patient monitoring display.

Combining the functions of the DSC-XP and the BIS algorithm into a single enclosure provides our OEM Business Partners with a more durable, more compact, and less expensive way to include the BIS Index parameter into their patient monitoring systems.

Indications for Use

BISx is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. It 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.

Summary of Technological Characteristics Compared to Predicate Device

Similarities

- The indications for use are identical.
- The fundamental technology has not changed, in that the BIS technology remains the same
- The BISx has the same operating principal in that both acquire raw EEG using the same signal processing, both filter and digitize EEG, and both calculate BIS.
- Functionality is the same in that there is a DSC (digital signal processor) and BIS algorithm that function using the same technology as the predicate device.
- Both have 2 channel maximum EEG monitoring capability.

Minor Differences

- DSC-XP and BIS algorithm are housed together in a single enclosure. In the predicate device, the algorithm resides within the Monitor, and the DSC-XP is a separate enclosure.
- The BISx has 2 printed circuit boards. In the predicate device, there are 4 printed circuit boards (2 in the DSC-XP, and 2 in the Monitor).
- Source code differs in that there are additional commands and additional messages that have been incorporated in the BISx, such as: new command for a sensor impedance check, and a command for a hardware id type.
- There are additional communication protocols
- There is more memory in the BISx. Also, the DSP processor is faster.

Testing

The following analysis/verifications/validations were performed:

- Risk analysis
- Software validation
- Electronic verification
- Mechanical/environmental validation

Results show all tests/analyses PASS. Therefore, the device is substantially equivalent to the predicate device, and safe for its intended use.

Conclusion

Based on the above, Aspect Medical Systems believes the BISx 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. Ned E. Devine
Entela Inc.
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

Re: K040183
Trade/Device Name: BISX
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLW, OMC, ORT, OLT
Dated (Date on orig SE ltr): February 11, 2004
Received (Date on orig SE ltr): February 12, 2004

APR - 9 2012

Dear Mr. Devine:

This letter corrects our substantially equivalent letter of February 25, 2004.

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

Indications for Use

510(k) Number (if known):

Device Name: BISx

Indications For Use:

The BISx is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. It 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.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhem

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

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