K002734

V 510(k) SUMMARY

SEP 1 4 2000

Date: August 31, 2000

Aspect Medical Systems, Inc., 141 Needham St. Newton, MA 02464
Contact Person: Christine M. Vozella (617) 559-7028

Proprietary Name: Aspect Medical Systems Pediatric EEG BIS Sensor
Common Name: Electrode, Cutaneous Electrode
Classification: Class II device. Refer to 21 CFR 882.1320.

Predicate device: Aspect Medical Systems EEG Sensor (BIS), 510(k) #K994330, clearance date 1/18/00

The Aspect EEG Enhanced BIS Sensor is a single patient use, low impedance, disposable EEG electrode sensor array with 4 electrodes that is designed for application to the frontal/temporal area to enable recording of electrophysiological (such as EEG) signals. It has an electronic smart card memory device in the tab area that contains configuration and identification information.

Indications for use: Applied directly to the patient's skin to enable recording of electro-physiological (such as EEG) signals.

Differences:

- Add an additional electrode to the sensor (3 to 4)
- Sensor dimensions are changing, i.e. there are cut-outs at the new electrode site to accommodate the roundness of the head at the application site (above the eye)
- The Sensor will be placed at an angle rather than straight across the forehead
- Tab (non skin contacting) is composed of polycarbonate, rather than ABS
- The BIS algorithm is being modified in conjunction with these changes. Aspect believes the changes will improve robustness too high frequency/EMG conditions, as well as improve performance during deep anesthetic/EEG states (such as near suppression in cardiac surgery).

Similarities:

- Indications for use are identical, i.e. to enable recordings of electrophysiological (such as EEG) signals.
- Same operating principle
- Same ease of use and low impedance function
- Same basic design
- Same packaging (different shade of color to distinguish between Aspect predicate and subject device)
- Both use the same patented Zipprep technology
- Skin contacting materials are identical

Testing:	Results:
Biocompatibility testing	All tests passed
Shelf life testing	
Electrical and mechanical testing	
Enhanced Sensor clinical evaluation	
A correlation between clinical utility, currently marketed and modified algorithms was completed	
Software validation testing was performed on the modified algorithm	
Evaluation of BIS algorithm performance	
Prospective clinical study of currently marketed and modified BIS algorithm	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 4 2000

Ms. Christine M. Vozella
Director, Regulatory Affairs and
Quality Assurance
Aspect Medical Systems, Inc.
141 Needham Street
Newton, Massachusetts 02464-1505

Re: K002734
Trade Name: Aspect Medical Systems Enhanced BIS Sensor
Regulatory Class: II
Product Code: GXY
Dated: August 31, 2000
Received: September 1, 2000

Dear Ms. Vozella:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Diane R. Lechner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K002734

DEVICE NAME: Aspect EEG Enhanced BIS Sensor

INDICATIONS FOR USE:

The Aspect EEG Enhanced BIS Sensor is applied directly to the patient's skin to enable recordings of electrophysiological (such as EEG) signals.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use ____
(Optional Format 1-2-96)

Donna R. Lochner
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002734