

K 994330

JAN 18 2000

V 510(k) SUMMARY

Prepared December 21, 1999

Company Name and Address

Aspect Medical Systems, Inc
2 Vision Drive
Natick, MA 01760-2059

Contact Person: Christine Morgida
Manager, Regulatory Affairs and Quality Assurance
Telephone: (508) 653-0603 x2026

Device Name

Proprietary Name: Aspect Medical Systems EEG Sensor
Common Name: Electrode, Cutaneous Electrode

Classification

Cutaneous Electrodes have been classified by the Neurological Devices Panel as Class II devices. Refer to 21 CFR 882.1320.

Predicate Device

Aspect Medical Systems Zipprep EEG Sensor
510(k) #K961821, clearance date 10/4/96

Description

The Aspect Medical Systems, Inc. EEG Sensor (hereafter referred to as the Aspect Sensor, Aspect EEG Sensor, or BIS Sensor +), is a rectangular shaped, pre-gelled array of three (3) Zipprep ® electrodes that is applied to the patient's skin to record electro-physiological (such as EEG) signals.

It is a low impedance, single patient use, disposable electrode sensor that is designed for application to the frontal/temporal area. The Aspect Sensor is designed to provide ease of use and electrode placement accuracy. It is used in conjunction with Aspect monitors.

The main body of the Aspect Sensor, which houses two (2) electrodes, is placed on the forehead. The satellite area, which houses one (1) electrode, is placed over the temple area. The Aspect Sensor collects EEG signals from these areas, and the differential signal from the temple to the center of the forehead is used to calculate the BIS. The area and distance between electrodes was chosen for ease of application, and to obtain maximum amplitude of the EEG signal, with a minimum of artifact.

The “Zipprep” patented electrode design is constructed using flexible tines mounted on a polyethylene basepad with an adhesive. The flexible tines, surrounded by hydrogel, are used to part the outermost layer of skin. While the flexible tines part the skin, hydrogel flows around the tines and forms a conductive bridge with the skin.

The Aspect Sensor connects to a monitor at a single point (tab) that is low profile and easy to insert and remove. The tab has an electronic smart card memory device that contains configuration and identification information. This allows better tracking/traceability of the product for Aspect, as well as communicating product information to the user.

All materials are biocompatible, and have been tested in accordance with ISO 10993. Skin contacting materials are the same as the Predicate Device.

Indications for Use

The Aspect Sensor is applied directly to the patient’s skin to enable recording of electro-physiological (such as EEG) signals.

Summary of Technological Characteristics

The Aspect Sensor has the same technological characteristics with regard to Zipprep design, some configuration capability, and materials. However, the smart card memory device, with its expanded configuration capabilities, could be considered a minor technological difference, in that with the addition of the smart card memory device, configuration capabilities are expanded further. The smart card memory device contains information concerning the lot number, date of manufacture and expiration date.

Summary of Testing

Aspect Medical Systems has conducted electrical and mechanical testing on the Sensor. In addition, software and hardware testing (including EMI testing) were conducted on the components of the system affected by the inclusion of the smart card memory device.

All tests passed in accordance with their specification.



JAN 18 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Christine Morgida
Manager, Regulatory Affairs
and Quality Assurance
Aspect Medical Systems, Inc.
2 Vision Drive
Natick, Massachusetts 01760-2059

Re: K994330
Trade Name: Aspect Medical Systems EEG Sensor, Model 186-0076
Regulatory Class: II
Product Code: GXY
Dated: December 22, 1999
Received: December 23, 1999

Dear Ms. Morgida:

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.

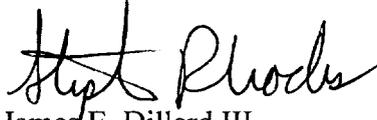
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

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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,

A handwritten signature in black ink, appearing to read "James E. Dillard III". The signature is written in a cursive style with a large, stylized initial "J".

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

**510(k)
Number**
(if known)

K 99 4330

Device Name

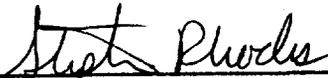
Aspect Medical Systems, Inc. EEG Sensor (BIS Sensor +)

**Indications for
Use**

The EEG Sensor (BIS Sensor +) is applied directly to the patient's skin to enable recording 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)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994330

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____