K050313

FEB 2 4 2005

510(k) Summary

Date:	January 20, 2005
Company:	Aspect Medical Systems, Inc., 141 Needham St., Newton, MA 02464
Contact Person:	Christine Vozella phone: 303-926-5624 fax: 303-604-6477
Proprietary Name:	Aspect Medical Systems BIS SRS
Common Name:	Electrode, Cutaneous Electrode
Classification:	Class II device. Refer to 21 CFR 882.1320
Predicate Devices:	The Aspect Enhanced BIS Sensor, K002734, cleared September 14, 2000 and the Aspect Zipprep Electrode, K940802, cleared June 22, 1994
Device Description:	The BIS SRS (Semi-reusable sensor) is a single patient use, disposable, pre-gelled 4 electrode array with a patented Zipprep design that is applied directly to the patient's forehead to record electro-physiological signals. The electrodes have a standard snap construction. There is an electronic smart card memory device in the multiple use cable. The SRS will be packaged as a set, composed of 100 disposable electrode arrays along with 1 multiple use cable.
Indications for Use:	The BIS SRS is applied directly to the patient's skin to enable recordings of electrophysiological (such as EEG) signals.

Similarities:

- same indications for use as the Predicate devices
- 4 electrodes – same as Enhanced BIS Sensor predicate device
- same operating principle (Zipprep technology) as both predicate devices
- same biocompatible skin contacting materials as the Zipprep Electrode predicate device
- same standard snap and eyelet construction as the Zipprep Electrode predicate device

Differences:

- minor construction differences
- smart card memory device is located in the multiple use cable rather than the sensor paddle
- No flexible circuit technology

Electrical and mechanical testing was conducted. Results indicate the device is safe for its intended use.

Aspect Medical Systems believes these modifications do not raise new questions of safety or effectiveness. The intended use is the same as both predicate devices. The fundamental scientific technology remains the same as the predicate devices. In summary, the BIS SRS described in this submission is substantially equivalent to the predicate devices.

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, Jr.
Entela Inc.
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

APR - 9 2022

Re: K050313
Trade/Device Name: BIS SRS (Semi-Reusable Sensor)
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: II
Product Code: GXY
Dated (Date on orig SE ltr): February 7, 2005
Received (Date on orig SE ltr): February 9, 2005

Dear Mr. Devine:

This letter corrects our substantially equivalent letter of February 24, 2005.

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,

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)

Device Name	BIS SRS (Semi-Reusable Sensor)
Indications For Use	The Aspect Medical Systems Semi-Reusable Sensor is applied directly to the patient's skin to enable recordings of electrophysiological (such as EEG) signals.

Prescription Use __X_____ (Per 21 CFR 801 Subpart D)

AND/OR

Over-The_Counter Use _____ (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)

Miriam C. Provost

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

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