K052981

12) 510(k) Summary

NOV - 1 2005

Company name and address: Aspect Medical Systems, 141 Needham St., Newton, MA 02464

Device name: BISx4

Classification: Class II, classification code: GWQ

Predicate device: Aspect Medical Systems BISx

Device Description

The BISx4 is a device that houses both the EEG digital signal converter, as well as the host interface software and BIS algorithm. The device will acquire up to four channels of referential EEG and compute BIS and other EEG parameters.

The BISx4 will have no display or user interface. Aspect Medical Systems is submitting this 510(k) in response to anesthesiologists/users who are interested in obtaining more than 2 channels of EEG.

Intended use: The BISx4 is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. The BISx4 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/differences)

The BISx4 is similar to the BISx (predicate device).

Similarities: Same design, technology, indication for use, same enclosure, both possess host interface software, BIS algorithm and a digital signal converter (DSC), both have 2 channels, both process BIS, both process parameters such as EEG, SQI, BIS, EMG, Signal Quality Index , (SQI), Suppression Ratio (SR), electrode impedance.

Differences: Addition of 2 channels, with accompanying changes to connectors, software, cables and yoke to enable acquisition of 4 channels.

Testing: Software, electrical, hazard analysis, EMI statement

Conclusion: The BISx4 is substantially equivalent to the BISx predicate device, and is safe and effective for its intended use.

Third Party Review Quality Assessment

Section 1 – Submission Information

510(k) No.: K052981 Third Party Organization: Intertek Testing Services NA

Third Party's Primary Reviewer(s): Jay Kogoma

ODE/OIVD Division: DGRND Branch/Team: GSDB

Section 2 – 510(k) Decision

Third party recommendation: SE X NSE ___ Other (specify): ___

ODE/OIVD final decision: SE X NSE ___ Other (specify): ___

Section 3 – Assessment of Third Party Review

Review Element	Rating (check one)		
	Adequate	Minor Issue(s)	Major Issue(s)
a. Determination of device eligibility for third party review	✓		
b. Extent of pre-submission consultation with ODE/OIVD division	✓		
c. Organization and format of review documentation	✓		
d. Determination of 510(k) administrative completeness (screening review)	✓		
e. Summary of device characteristics, intended use, and performance (including accessories, if applicable) and reason for 510(k) submission	✓		
f. Comparison to legally marketed devices—identification and analysis of key similarities and differences	✓		
g. Rationale for conclusions and recommendation	✓		
h. Use of guidance documents and standards	✓		
i. Resolution of 510(k) deficiencies and FDA requests for additional information			
j. Scope of reviewer expertise and use of consulting reviewers	✓		
k. Other (specify):			

Comments (explanation of ratings/issues): Well prepared review. No issues

Section 4 – ODE/OIVD Assessor Information

Assessed by: Michel Janda Date: 10/28 Tel. No.: (301) 594-1307 x137

Routing: Division--Clip completed assessment (this page only) to inside front cover of 510(k).
DMC--Forward this page only to Eric Rechen, POS/ODE, Rm. 120J, Corp. Blvd. (HFZ-402).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 1 2005

Aspect Medical Systems, Inc.
c/o Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Inc.
70 Codman Hill Road
Boxborough, Massachusetts 01719

Re: K052981
Trade/Device Name: BISx4
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: October 21, 2005
Received: October 24, 2005

Dear Mr. Lehtonen:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052981

Device Name: **Aspect Medical Systems, Inc. BISx4**

Indications for Use:

The BISx4 is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. The BISx4 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_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

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

510(k) Number K052981

(Posted November 13, 2003)