

JUN 23 2006
510(k) Premarket Notification **K060900**

Spacelabs Medical
Bispectral Index (BISx) Analysis Module 91482 and Accessories
Summary of Safety and Effectiveness

May 15, 2006

The 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 1992.

Subject: 510(k) Summary of Safety and Effectiveness Information for the Spacelabs Medical Bispectral Index (BISx) Analysis Module 91482

Submitter: Spacelabs Medical, Inc.
PO Box 7018
Issaquah, WA 98029

David J. Geraghty
Phone: 1 425 657 7200
Fax: 1 425 657 7207
david.geraghty@slmd.com

Proprietary Name: Spacelabs Medical Bispectral Index (BISx) Analysis Module, model 91482

Common Name and Classification: Electroencephalograph (EEG) Monitor
(84 GWQ, §882.1400, Class II)

Device Description: The Spacelabs Medical Bispectral Index (BISx) Analysis Module 91482 (BISx Module 91482) is an easy-to-use, slim, single module in the Spacelabs Medical family of Spacelabs Medical Ultraview System (Ultraview) modules. The BISx Module 91482 is a microprocessor based, two-channel EEG unit designed for use on adult and pediatric patients within a hospital or medical facility. Its system configuration includes the BISx Module 91482 with connectors for external serial data connections, a BISx pod, a patient interface cable, disposable sensors, and printer options. The BISx pod, patient interface cable and disposable sensors are manufactured by Aspect Medical Systems, and distributed by Spacelabs Medical for use with the BISx Module 91482. The Spacelabs Medical Ultraview monitor provides the display capabilities for the care provider.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Spacelabs Medical Inc.
c/o Mr. David J. Geraghty
Manager, Regulatory and Quality
P.O. Box 7018
Issaquah, Washington 98027

APR - 9 2012

Re: K060900

Trade/Device Name: Spacelabs Medical Bispectral Index (BIS) Analysis Module 91482 and Accessories

Regulation Number: 21 CFR 882.1400

Regulation Name: Electroencephalograph

Regulatory Class: II

Product Code: OLW, OMC, OLT, ORT

Dated (Date on orig SE ltr): May 23, 2006

Received (Date on orig SE ltr): May 25, 2006

Dear Mr. Geraghty:

This letter corrects our substantially equivalent letter of June 23, 2006.

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.

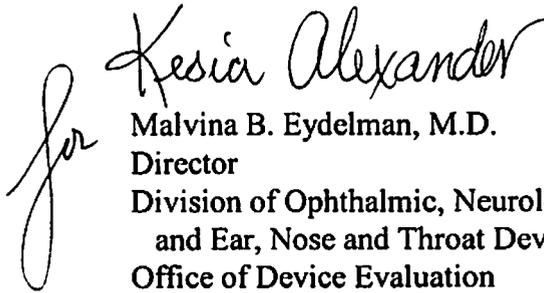
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,

A handwritten signature in cursive script that reads "Kesia Alexander". To the left of the signature is a large, stylized cursive "for" written vertically.

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

