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K973596

510(k) SAFETY AND EFFECTIVENESS SUMMARY

Spacelabs Medical 90482 Bispectral Index Analysis (BIS) Module

1. Submitter's Name: Russ Garrison
   Director of Regulatory Affairs

   Company: Spacelabs Medical Inc.
   15220 N.E. 40th Street
   Redmond, WA 98073

   Telephone: (425) 882-3913

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2. Name of Device: Spacelabs Medical 90482 BIS Module

   Classification: Electroencephalograph (EEG) Monitor
   OLW, ORT, OLT, OMC

3. Predicate Device: We consider the Spacelabs Medical 90482 BIS Module to be substantially equivalent to the EEG Monitor, Models A-1000/A-1050 with the Processed Parameter BIS, currently marketed by Aspect Medical Systems, Inc. (510[k] reference K963644). Both monitoring systems provide the means to monitor the state of the brain by data acquisition and processing of EEG signals in a clinical hospital environment or research setting. Both also use the identical bispectral analysis algorithm, a processed EEG variable displayed as a numerical value, as an aid in monitoring the effects of certain anesthetic agents. The bispectral analysis algorithm used in the Spacelabs Medical 90482 BIS Module has been licensed from Aspect Medical Systems and the 90482 BIS Module uses a Digital Signal Converter (DSC-2) and a proprietary sensor developed by Aspect Medical to operate in the BIS mode.

4. Device Description:

The Spacelabs Medical 90482 BIS Module is a slim, lightweight singular modular unit that, when used in conjunction with a Spacelabs Medical Patient Care Information System (PCIS), provides the capability to acquire, process and display one (1) or two (2) channels of brain electrical activity (EEG). The EEG data is processed to derive a Bispectral Index (BIS) to correlate the EEG activity to the state of the brain. Other trended parameters may also be processed, including spectral edge frequency, electromyogram activity, median power frequency, a signal quality index, and suppression of the EEG signal.

The Module is the primary interface to the patient being monitored. The Module is capable of acquiring and processing EEG signals for a single patient. The Module accumulates the patient physiological data of interest and provides both waveform and digital data to a Spacelabs Medical Patient Care Information System (PCIS) monitor via SDLC communications. The PCIS system provides the display, review and editing capabilities for the care provider.

5. Intended Use:

The Spacelabs Medical 90482 BIS Module is intended to monitor the state of the brain by data acquisition of EEG signals in the intensive care unit, operating room and for clinical research. The Bispectral Index (BIS), a processed EEG variable, may be used as an aid in monitoring the effects of certain anesthetic agents.

6. Comparison of Technological Characteristics:

The design, components, storage technology and energy source of the 90482 BIS Module are similar to its predicate device. Both the 90482 BIS Module and the Aspect EEG/BIS Monitor provide the means for interfacing with a patient, collecting EEG data, and processing the data for alarm generation and display of EEG waveforms and numeric BIS values on a bedside or central monitoring system. The bispectral analysis algorithm has been licensed from Aspect Medical and, to operate in the BIS mode, a specific proprietary sensor provided by Aspect Medical Systems must be used.

	The only significant difference between the Spacelabs Medical BIS Module and the comparable system marketed by Aspect Medical are in the hardware packaging of the 90482 BIS Module, which is designed for modular compatibility with the Patient Care Monitoring System (PCIS) currently offered by Spacelabs Medical.
7. Testing:	The Spacelabs Medical 90482 BIS Module will be subject to extensive safety and performance testing prior to release. Final testing for the system includes various performance tests designed to ensure that the device meets all of its functional requirements and performance specifications. Safety testing will be performed by third party agencies to ensure the device complies to applicable industry and safety standards for medical devices, including UL2601-1, C222.2 No. 601-1, and IEC 601-1, and, for the safety of electroencephalographs specifically, IEC 601-2-26.

In conclusion, the Spacelabs Medical 90482 BIS Module is as safe and effective as the predicate device currently marketed by Aspect Medical Systems and raises no new safety or effectiveness issues.

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

Mr. Russ Garrison
Director of Regulatory Affairs
Spacelabs Medical, Incorporated
15220 North East 40th Street
Redmond, Washington 98073

APR - 9 2012

Re: K973596
Trade/Device Name: Spacelabs Medical 90482 Bispectral Index Analysis (BIS) Module
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLW, ORT, OLT, OMC
Dated (Date on orig SE ltr): December 18, 1997
Received (Date on orig SE ltr): December 22, 1997

Dear Mr. Garrison:

This letter corrects our substantially equivalent letter of February 3, 1998.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

510(k) Number (if known): Not Known (New Submission) K973596

Device Name: Spacelabs Medical 90482 Bispectral Index Analysis (BIS) Module

Indications for Use:

Condition to be screened, monitored, treated or diagnosed.
Patient conditions indicated by abnormalities in electroencephalograph (EEG) signals in the brain.

Prescription use only.
Yes. Caution statement is provided in the introductory page of the Patient Care Information System which includes the operating instructions for this Module.

Parts of body applied to.
Electrodes connected to the Module are applied externally to the scalp.

Frequency of use.
Frequency as directed by physician.

Physiological purpose.

- To monitor the state of the brain by data acquisition of EEG signals in the intensive care unit, operating room and for clinical research, and
- To display a Bispectral Index (BIS), a processed EEG variable, which may be used as an aid in monitoring the effects of certain anesthetic agents.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use _____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973596