K103142

MAR - 3 2011

510(k) Summary

Submission Date:	17 December 2010
Submitter Correspondent:	Spacelabs Healthcare 5150 220th Avenue SE Issaquah, WA 98029 Mr. David J. Geraghty Spacelabs Healthcare Phone: +1 (425) 657-7200, ext 5889 Fax: +1 (425) 657-7210 Email: david.geraghty@spacelabs.com
Application Correspondent:	Speed To Market, Inc. PO Box 3018 Nederland, CO 80466 Mr. Thomas Kroenke Phone: +1 (303) 956-4232 Fax: +1 (303) 642-3141 Email: tkroenke@speedtomarket.net
Trade Name:	Spacelabs Multi-parameter Module
Common Name:	Arrhythmia Detector and Alarm
Classification Name:	Detector and Alarm, Arrhythmia
Classification Regulation:	21 CFR §870.1025, 21 CFR §870.2710, 21 CFR §870.2700, 21 CFR §870.1110, 21 CFR §870.1435, 21 CFR §870.1130, 21 CFR §880.2910, 21 CFR
Product Code:	DSI, DPZ, DQA, DSK, DXG, DXN, FLL, LOS

Substantially Equivalent Devices:

New Spacelabs Model	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
Spacelabs Multi-parameter Module	K050605	Spacelabs Medical Inc. / Spacelabs Medical Multi-parameter, Module 91496

Device Description:

The Spacelabs Multi-parameter Module provides monitoring capability for the following parameters: ECG with arrhythmia detection, respiration, invasive and noninvasive blood pressure, temperature, oxygen saturation (SpO2) and cardiac output. It is a "plug-in" module that is used in conjunction with a Spacelabs Monitoring Station such as the Model 91387.

The patient is connected to the Spacelabs Multi-parameter Module via parameter-specific cables/sensors which provide the monitor with the patient's physiological data. The physiological data for each active parameter is accumulated by the Spacelabs Multi-parameter Module, and sent to the monitor which performs any necessary analysis and provides both waveform data and numeric values for display on the monitor screen. The monitor provides the display and printing capabilities for the care provider.

Setting of alarm limits, enabling or disabling alarm monitoring, and definition of alarm responses are determined on a parameter-by-parameter basis, and can be defined by the user for each parameter. In general, alarm limits can be set to provide the user with both audible and visible indications of the alarm condition. Each parameter provides a hierarchy of menu structures and keys that are activated through controls of the monitor by touching the monitor screen.

Each parameter provides the capability to output recordings of selected information to a variety of recording devices. Recordings are available using the Spacelabs Monitor internal printer, network printers, and the Intesys Clinical Suite Print Manager Model 91881. Recordings can be automatically generated by each of the parameter's alarm managers or manually generated.

Technology Comparison:

The Spacelabs Multi-parameter Module utilizes the same technology for each parameter as utilized by the predicate device.

Intended Use:

The Spacelabs Multi-parameter Module is intended for use with the Patient Care Management System (PCMS) to acquire, monitor, and process various clinical parameters from an adult or neonate/infant populations in any type of clinical environment other than home use.

Physiological parameters that may be monitored include ECG with arrhythmia detection, respiration, invasive and noninvasive blood pressure, temperature, oxygen saturation (SpO2) and cardiac output. Acquired data may then be communicated to an information network for display, recording, editing and analysis.

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Performance Testing:

Sterilization and Shelf-Life	The Spacelabs Multi-parameter Module is not sterilized or sterilizable by the user. Accessories which may be sterilized or sterilizable by the user were not affected by the software device modifications made to the Spacelabs Multi-parameter Module. Therefore, this section is not applicable.
Biocompatibility	The Spacelabs Multi-parameter Module is not intended to directly or indirectly contact the patient. Accessories which may directly or indirectly contact the patient were not affected by the software device modifications made to the Spacelabs Multi-parameter Module. Therefore, this section is not applicable.
Software Testing	The software device modifications made to the Spacelabs Multi-parameter Module were designed and developed according to a robust software development process, and were rigorously verified and validated. Software information is provided in accordance with: • *FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05; and* • *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02.* Test results indicate that the Spacelabs Multi-parameter Module complies with its predetermined specification.
Electrical Safety and Electromagnetic Compatibility Testing	The software device modifications made to the Spacelabs Multi-parameter Module did not affect the electrical safety or electromagnetic compatibility performance of the device. No hardware modifications were made to the device; therefore this section is not applicable.
Performance Testing – Bench	In addition to the software verification and validation performed, the software device modifications made to the Spacelabs Multi-parameter Module were testing in accordance with ANSI/AAMI EC57: 1998 / (R) 2003. Test results demonstrate performance equal to or better than the predicate device.
Performance Testing – Animal:	Animal performance testing is not necessary to demonstrate safety and effectiveness of the Spacelabs Multi-parameter Module. Therefore, this section is not applicable.
Performance Testing – Clinical:	Clinical performance testing is not necessary to demonstrate safety and effectiveness of the Spacelabs Multi-parameter Module. Therefore, this section is not applicable.

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Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of the software device modifications made to the Spacelabs Multi-parameter Module. The results of these activities demonstrate that the Spacelabs Multi-parameter Module is safe and effective when used in accordance with its intended use and labeling.

Therefore, the Spacelabs Multi-parameter Module is considered substantially equivalent to the predicate device.

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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

Spacelabs Healthcare Inc.
c/o Mr. Thomas Kroenke
Speed To Market, Inc
PO Box 3018
Nederland, CO 80466

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Re: K103142
Trade/Device Name: Spacelabs Multi-parameter Module
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II (two)
Product Code: DSI, DQA, DSK, DXG, DXN, FLL
Dated: February 7, 2011
Received: February 10, 2011

Dear Mr. Kroenke:

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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103142

Device Name: Spacelabs Multi-parameter Module

Indications for Use:

The Spacelabs Multi-parameter Module is intended for use with the Patient Care Management System (PCMS) to acquire, monitor, and process various clinical parameters from an adult or neonate/infant populations in any type of clinical environment other than home use.

Physiological parameters that may be monitored include ECG with arrhythmia detection, respiration, invasive and noninvasive blood pressure, temperature, oxygen saturation (SpO2) and cardiac output. Acquired data may then be communicated to an information network for display, recording, editing and analysis.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

for BZuckerman

(Division Sign-Off) 3/3/2004
Division of Cardiovascular Devices
510(k) Number K103142