K102422

510(k) Special Premarket Notification
Spacelabs Healthcare, Inc.
Spacelabs Patient Monitors
Summary of Safety and Effectiveness

DEC - 7 2010

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

Date Prepared	15 November 2010
Subject:	510(k) Summary of Safety and Effectiveness Information for the Spacelabs Medical Ultraview SL Patient Monitors
Submitter:	Spacelabs Medical, Inc. 5150 220th Ave SE Issaquah, WA 98029-6834 David J. Geraghty Phone: 1 425 657 7200 Ex 5889 Fax: 1 425 657 7210 david.geraghty@slmd.com
Establishment Registration Number:	3023361
Proprietary Name:	Spacelabs Medical Patient Monitors Model Number 91367, 91369, 91370 and 91387
Common Name	Patient Monitors
Classification:	Monitor, Physiological, Patient (with Arrhythmia Detections) Product Code 74 MHX; 21CFR 870.1425. Class II
Performance Standard:	The FDA has promulgated the *Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm* for this product classification. NOTE: Arrhythmia functionality is implemented in the Spacelabs Medical Multiparameter Module, model 91496, not part of this submission. The model 91496 was cleared under K050605.
Predicate Devices	Device Name: Spacelabs Medical PCIS Patient Monitors 510(k) Number: K972282 Manufacturer: Spacelabs Medical Inc.

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Device Description: The Spacelabs Medical Patient Monitors are a component of the Spacelabs Medical Patient Monitoring System. The four (4) monitor models; portable models 91367, 91369 and 91370 and the stationary monitor model 91387; are all similar in that they are all employ the same software and all accept inputs from the family of Spacelabs Parameter Modules. The monitors accept and display parameter information, waveform and numeric data, and alarm conditions including arrhythmia information received from the same family of modules modules. (See table).

Parameter(s)	Model Number	Description / Comments	510(k)
Anesthesia Gas • CO2 • 02 • N20 • Desflurane; • Enflurane; • Halothane; • Isoflurane; • Sevorflurane.	91518	Multigas Analyzer Module	K053599
• Carbon dioxide. • Oxygen.	91517	Capnography Module	K031124
• ECG, • SpO2, • NIBP (optional)	90478	Telemetry Receiver Module, Requires transmitter module	K925510
• ECG, • Respiration, • Invasive Blood Pressure, • Non-Invasive Blood Pressure • SpO2, • Temperature, • Cardiac Output	91496	Ultraview SL™ Command Module	K050605
ECG	90492	12-Lead ECG Module	K942058
EEG, Dual Channel	90480	EEG Module	K932842
EEG	90481	EEG Module	K932842
EEG	91482	BISx Module	K060900
Mixed venous oxygen saturation	91424	SVC/$ScVO_2$ Module	K893867
Thermal printer	90469	2/4 channel printer Module	K842616
Thermal printer	90449	2 channel printer Module	K842616

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Parameter(s)	Model Number	Comments	510(k)
Interface to External Device	90442-A	Flexport Interface Module; UNIVERSAL FLEXPORT	K903702
	90421	Flexport Interface Module, Compatible with: o NOVA515 o NELLCOR o OHMEDA	
	90433	Flexport Interface Module, Compatible with: o NORMOCAP CD-02 o NELLCOR,N-2500 o DATEX CAPNO II o DATEX PB254 o 5200 o N1260 o DATEX PB254	
	90434	Flexport Interface Module, Compatible with: o NOVAMETRIX 7000 o NELLCOR N1000 o CRITICARE POET	
	90435	Flexport Interface Module, Compatible with: o DINAMAP,8100,NIBP o DINAMAP NIBP	

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Parameter(s)	Model Number	Comments	510(k)
Interface to External Device (Continued)	90436	Flexport Interface Module, Compatible with: o PB7200 W/ANALOG INTRFC o PB7200 W/ANALOG INTRFC o VELA, VIASYS VENT o DRAGER EVITA 4 VENT o PB840,VENTILATOR INTERFACE o ET/A,FLEXPORT,ENGSTROM ERICANGSTROM ELVIRA o ENGSTROM ERICA/ELVIRA o BEAR 1000 o DRAGER NARKOMED 2B,2C o DRAGER EVITA 2 & EVITA 2 DURA o DRAGER,VENT,INTRFC o OHMEDA 7800/10,INTRFC o HAMILTON,VENT,INTRFC o INFANTSTAR INTRFC o ADULTSTAR o SIEMENS S300 o SIEMENS S990 o INFANT STAR INTFCRT PB7200A/RESPIRONICS ESPRIT o SIEMENS S990 o PB7200A	K903702
	90437	Flexport Interface Module, Compatible with: o BRAUN BCC o BAXTER FLO-GARD o ABBOTT PLUM o IVAC INFU PMP o IMED INFU PMP o ABBOTT INFU PMP	
	90438	Flexport Interface Module, Compatible with: o NOVAMETRIX 840/860 o TRANSCUTANEOUS ANAL	

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Parameter(s)	Model Number	Comments	510(k)
Interface to External Device (Continued)	90439	Flexport Interface Module, Compatible with: o PULSION PICCO o PULSION PICCO,INTERFACE,90439	K903702
	90443	Flexport Interface Module, Compatible with: o DRAGER CICERO EM o DRAEGER CATO o OHMEDA RASCAL II o ENGSTROM,EAS o DRAGER CICERO-B o DATEX ULTIMA W/ANALOG o OHMEDA,RGM o NARKOMED I o BICORE	
	90444A	Flexport Interface Module, Compatible with: o INCUBATOR INTFC OHMEDA	
	90451	Flexport Interface Module, Compatible with: o Spacelabs FETAL MONITORS	
	90519	Flexport Interface Module, Compatible with: o 90519B,BASE UNIT	
	91436	Flexport Interface Module, Compatible with: o RADIOMETER ,91438A o GE CARESTATION,91436E o ENGSTRÖM,91436E o GE AVANCE o GE AVANCE,91436D o VIASYS ,91436C o SERVO I ,91436B o PULMONETICS	
	91438	Flexport Interface Module, Compatible with: o RADIOMETER ,91438A o GE ENGSTRÖM CS	

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The portable monitors are capable of operating independent of or connected to the Spacelabs Patient monitoring Network. As independent, portable monitors these devices operate from either AC or battery power. All alarm information received from the parameter modules is visually and audibly available at each monitor. When networked, either physically or wirelessly, these monitors are able to share their information with a central station or with other monitors on the network according to conditions establish by the user/system administrator. They are also able to connect, via the healthcare institution's network, through Dynamic Network Access (DNA) to other applications available on the network.

The stationary monitor, model 91387, can be configured at installation as either a bedside or central station. As an independent bedside monitor the device operates from AC and. presents waveform, numeric data, and alarm conditions, including arrhythmia information, received from parameter modules. When physically networked these monitors are able to share their information with a central station or with other monitors on the network according to conditions establish by the user/system administrator. They are also able to connect, via the healthcare institution's network, through Dynamic Network Access (DNA) to other applications available on the newt6work.

The model 91387 central station monitor provides full monitoring control of remote parameters, including displays and alarms with both visual and audible annunciation for up to 16 patients. All waveform and current numeric data, arrhythmia, ST segment, and trends are available are available at the central station.

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Comparison to Predicate Device

The models 91387, 91367, 91369 and 91370 monitors are substantially equivalent to their predicate device, the Spacelabs Medical PCIS Patient Monitors, models 90364 and 90369. All devices offer the same parameter monitoring capabilities, dependant on the parameter modules employed. The portable 91367, 91369 and 91370 may be used as a bedside or transport monitors, the same as their predicate, the model 90369. The 91387 may be used as a bedside or central station, similar to its predicate, the 90364.

The following changes were incorporated when the monitors moved from the 90XXX to 91XXX;

Change made to plastic material (remained PVC) giving the patient monitor a "new look". CPU boards and internal DC power supplies were also updated during this project, no functional change were made.

The maximum parameter capacities of the 91387 are the same as its predicate. The number of parameters displayed at one time, for the portable models 91367, 91369 and 91370, was adjusted to accommodate the different display sizes.

The number of internal module slots and the maximum number of remote module housings available for use with parameter modules have not changed for the 91387 and 91367, 91369 or 91370 from their predicate.

Display resolution has also been expanded on the 91387 and 91370 portable as technology became available. Where the 90364 was 768/1024, the 91387 resolution has been increased to 1024/768. All but one of the Spacelabs portable monitors remained identical to the predicate 90369 display resolution, with only the 91370 supporting a higher 1024/768 resolution.

The CPU PCBA (670-1275-XX) maintenance release was implemented to improve production yield. Changes were also made as a result of employing digital signal integrity analysis tool, resulting improved signal integrity of the circuit board assembly.

The operating system was updated with the release of 2.03.0X software for the 91387, 91367, 91369 and 91370 monitors. This update, supplied by VxWorks, and adapted by Spacelabs Medical allowed for implementation of a higher level of security for the DNA and Wireless network for the monitors, as well as updating various drivers such as USB.

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Intended Use:	Spacelabs Healthcare patient monitors, functioning as either bedside or central monitors; passively display data generated by Spacelabs Healthcare parameter modules, Flexports interfaces, and other SDLC based products in the form of waveform and numeric displays, trends and alarms. Key monitored parameters available on the model 91367, 91369, 91370 and 91387, when employing the Spacelabs Command Module, consist of ECG, respiration, invasive and noninvasive blood pressure, SpO2, temperature and cardiac output. Additional parameters and interfaces to other systems are also available depending on the parameter modules employed. Spacelabs Healthcare patient monitors are intended to alert the user to alarm conditions that are reported by Spacelabs Healthcare parameter modules and/or other physiologic monitors via Flexport interfaces. These devices determine a) when an alarm condition is violated; b) the alarm priority (i.e. high, medium or low); c) alarm limits; and d) when to initiate and terminate alarm notifications. The patient monitors are also capable of displaying alarm conditions on other monitors that are on the network through the Alarm Watch feature. Spacelabs Healthcare patient monitors may also function as a generic display or computer terminal. As a generic display or terminal, the patient monitors allow network-based applications to open windows and display information on other networked monitors. Spacelabs Healthcare patient monitors are also designed to communicate with a variety of external devices such as displays, network devices, serial devices, user input devices, audio systems, and local/remote recorders., Spacelabs Healthcare patient monitors are intended for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in proper use of the equipment in a hospital environment.
Test Discussion:	The Spacelabs Patient Monitors; models 91367, 39139, 91370 and 91387; are substantially equivalent in design concepts, technologies and materials to the predicate found substantially equivalent under K972282. The Spacelabs Patient Monitors were validated through rigorous testing that, in part, support the compliance of the software to the Standards mentioned in the Software section of this submission. Additionally, the Spacelabs Patient Monitors' software was developed following a robust software development process that was fully specified and validated. Test programs verified that parameter data provided by parameter modules, not part of this submission, to the Patient Monitors could be accurately presented and that the interface supported the intended clinical work flows and met the user's clinical needs.
Test Conclusion:	The Spacelabs Patient Monitors; models 91367, 39139, 91370 and 91387; are substantially equivalent to their predicate devices in design concepts, technologies and materials. Testing demonstrates that Spacelabs Patient Monitors are as safe and effective as the predicate devices found substantially equivalent under K972282.

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 Medical, Inc.
C/O David J. Geraghty
5150 220th Ave SE
Issaquah, WA 98029-6834

DEC - 7 2010

Re: K102422
Trade/Device Name: Spacelabs Patient Monitors
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II
Product Code: MHX
Dated: November 17, 2010
Received: November 18, 2010

Dear Mr. Geraghty:

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,

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

Enclosure

Indications for Use Form

510(k) Number (if known): **K102422**

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Device Name: Spacelabs Patient Monitor

Indications for Use:

Spacelabs Healthcare patient monitors, functioning as either bedside or central monitors; passively display data generated by Spacelabs Healthcare parameter modules, Flexports interfaces, and other SDLC based products in the form of waveform and numeric displays, trends and alarms. Key monitored parameters available on the model 91367, 91369, 91370 and 91387, when employing the Spacelabs Command Module, consist of ECG, respiration, invasive and noninvasive blood pressure, SpO2, temperature and cardiac output. Additional parameters and interfaces to other systems are also available depending on the parameter modules employed.

Spacelabs Healthcare patient monitors are intended to alert the user to alarm conditions that are reported by Spacelabs Healthcare parameter modules and/or other physiologic monitors via Flexport interfaces. These devices determine a) when an alarm condition is violated; b) the alarm priority (i.e. high, medium or low); c) alarm limits; and d) when to initiate and terminate alarm notifications. The patient monitors are also capable of displaying alarm conditions on other monitors that are on the network through the Alarm Watch feature.

Spacelabs Healthcare patient monitors may also function as a generic display or computer terminal. As a generic display or terminal, the patient monitors allow network-based applications to open windows and display information on other networked monitors.

Spacelabs Healthcare patient monitors are also designed to communicate with a variety of external devices such as displays, network devices, serial devices, user input devices, audio systems, and local/remote recorders.

Spacelabs Healthcare patient monitors are intended for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in proper use of the equipment in a hospital environment.

Prescription Use: **XX**
(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)

Diana R. Vaughn

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102422