K031124

DEC - 4 2003

1.5 510(k) Summary of Safety and Effectiveness

Model 95000-A Bedside/Transport Monitor

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.
Submitter	Spacelabs Medical, A Division of Datex-Ohmeda, Inc.
Contact Person	Al Van Houdt Spacelabs Medical 5150 220th Ave. SE P.O. Box 7018 Issaquah, WA 98027-7018 Telephone: 425-657-7200 x5970 FAX: 425-657-7210
Date Prepared	April 4, 2003
Name	Model 95000-A Bedside/Transport Monitor
Classification Names and Product Codes	Arrhythmia detector and alarm, DSI, §870.1025 Cardiac monitor, DRT, §870.2300 Carbon dioxide gas analyzer, CCK, §868.1400
Device Classification	Classification: Class III Classification Panel: Cardiovascular Devices
Predicate Devices	• Spacelabs 95000 Bedside/Transport Monitor, K013046 (cleared 08/02) • Spacelabs Comet Capnograph Module (90516), K941165 (cleared 10/94) • Novametrix CO_2SMO Plus Monitor (8100), K963380 (cleared 01/97)
Performance Standards	FDA has not established performance standards under sections 514 of the Federal Food, Drug and Cosmetic Act.
Device Description	The Model 95000-A Bedside/Transport Monitor is a multi-parameter patient monitor that is capable of acquiring, analyzing, monitoring and displaying a variety of physiological parameters including: electrocardiograph (ECG), respiratory effort, non-invasive blood pressure (NIBP), temperature, invasive blood pressure, pulse oxygen saturation (SpO2), cardiac output, carbon dioxide (CO2) and oxygen (O2).

Indications for Use	The Model 95000-A Bedside/Transport Monitor is used at the patient's bedside to actively acquire, analyze, monitor and display a variety of clinical parameters (in clinically relevant formats) for adults, pediatric or neonatal patients.
	
	The Model 95000-A Bedside/Transport Monitor is designed for use by a healthcare professional in a hospital, healthcare facility (ie, clinic), or intra-hospital transport. This product is not designed for home use or for use in transport vehicles.
	
	The Model 95000-A Bedside/Transport Monitor supports product configurations with almost any combination of clinical parameters that provide the following:
	
	• A means for continuous monitoring of:
	  • Electrocardiographic signals in order to detect:
	  • Normal cardiac rhythms, including life-threatening events such as high and low heart rates, asystole and ventricular fibrillation.
	  • (Adult patients only) Additional abnormal cardiac rhythms, such as ventricular runs and tachycardia, and ST segment deviations.
	  • Respiratory effort in order to detect abnormal respiration events such as high and low respiration rates and episodes or apnea.
	  • Invasive blood pressure in order to detect abnormal events such as high and low blood pressure.
	  • Pulse oxygen saturation in order to detect desaturation due to abnormal pulmonary or circulatory functions.
	  • Temperature in order to detect abnormal events such as high and low temperatures.
	  • Carbon dioxide.
	  • Oxygen.
	• A means for episodic monitoring of:
	  • Non-invasive blood pressure signals to detect abnormal events such as high and low blood pressure.
	  • (Adult patients only) Various hemodynamic values to detect abnormal cardiac flow (CO) values.

Substantial Equivalence	The Model 95000-A Bedside/Transport Monitor contains features and functions that were previously cleared in Spacelabs Medical's devices (K013046 and K941165). Therefore, The Model 95000-A Bedside/Transport Monitor is similar to the predicate devices in its information display, storage, trending and printing capabilities. Minor modifications were made to the Model 95000-A Bedside/Transport Monitor to make the device more versatile and to incorporate new technology.
Non-clinical Performance	Spacelabs Medical performed non-clinical testing on the Model 95000-A Bedside/Transport Monitor to confirm the safe and effective performance of the device. The test results indicate that the device functions as expected.
Conclusion	The Model 95000-A Bedside/Transport Monitor is substantially equivalent to the Spacelabs Medical's currently cleared and marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2003

Mr. Al Van Houdt
Director, Regulatory Affairs & Quality
Spacelabs Medical
5150 220th Avenue SE
Issaquah, Washington 98029

Re: K031124
Trade/Device Name: Polaris 95000-A Bedside/Transport Monitor
Regulation Number: 870.1025
Regulation Name: Physiological Patient Monitor (with Arrhythmia Detection or Alarms)
Regulatory Class: III (three)
Product Code: MHX, CCK, CCL
Dated: September 5, 2003
Received: September 8, 2003

Dear Mr. Van Houdt:

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 (301) 594-4646. 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/dsma/dsmamain.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K031124

Device Name: Model 95000-A Bedside/Transport Monitor

Indications For Use:

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  - Pulse oxygen saturation in order to detect desaturation due to abnormal pulmonary or circulatory functions.
  - Temperature in order to detect abnormal events such as high and low temperatures.
  - Carbon dioxide.
  - Oxygen.
- A means for episodic monitoring of:
  - Non-invasive blood pressure signals to detect abnormal events such as high and low blood pressure.
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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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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