K112729

JUN 1 1 2012

510(k) Premarket Notification
Spacelabs Healthcare
Blease 900 Series Ventilators
510(k) Summary

Submission Date:	24 May 2012
Submitter:	Spacelabs Healthcare Ltd. 1 Harforde Court, John Tate Road Hertford, SG13 7NW United Kingdom
Submitter Contact:	Mr. David J. Geraghty Spacelabs Medical, Inc. (for Spacelabs Healthcare, Ltd.) Phone: +1 (425) 657-7200, ext 5889 Fax: +1 (425) 657-7210 Email: david.geraghty@spacelabs.com
Official Contact:	Thomas Kroenke Principal Consultant Speed To Market, Inc. PO Box 3018 Nederland, CO 80466 USA tkroenke@speedtomarket.net 303 956 4232
Manufacturing Site:	Spacelabs Medical, Inc. 5150 220th Avenue SE Issaquah, WA 98029 USA
Trade Name:	Spacelabs Blease 900 Series Ventilators
Common Name:	Continuous Ventilator
Classification Name:	Continuous Ventilator
Classification Regulation:	21 CFR §868.5895
Product Code:	CBK

Substantially Equivalent Devices:	*New Spacelabs Model*	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
	Spacelabs Blease 900 Series Ventilators	K101850	Spacelabs BleaseSirius Anesthesia Workstation

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Device Description: The Spacelabs Healthcare (Spacelabs) Blease 900 Series Ventilators (Blease 900) are advanced, microprocessor-controlled, pneumatically driven ventilators, which have been designed specifically for the mechanical ventilation of adult and pediatric patients under general anesthesia.

The unit houses the electronic and pneumatic control systems. It sets the desired ventilatory parameters and generates alarm, warning and status messages. The control unit also calculates and implements the functions necessary to drive the bellows pneumatically.

The bellows assembly consists of a base and a bellows housing.

The Spacelabs Blease 900 are designed for use with a circle-type absorber, and is ideally suited to both low- and high-flow applications.

Model Number		*900 Series*		
		950	**970**	**990**
Screen size		8.4 inches	8.4 inches	8.4 inches
Display		Color	Color	Color
Interface		Touch and Trak	Touch and Trak	Touch and Trak
Tidal volume compensation				
Fresh gas compensation		Optional for OEM/ stand alone	Optional for OEM/ stand alone	Optional for OEM/ stand alone
Configurable preset or measured compliance		Yes	Yes	Yes
Adult, and pediatric		Yes	Yes	Yes
Ventilation mode				
Volume control		Yes	Yes	Yes
Pressure control		Yes	Yes	Yes
SIMV + PSV (Volume and pressure mode options)		Yes	Yes	Yes
Precision pressure support		No	Yes	Yes
Ventilation monitoring				
Oxygen		Yes	Yes	Yes
Inhaled and exhaled volume monitoring		Yes	Yes	Yes
Airway pressure		Yes	Yes	Yes
Pressure waveform		Yes	Yes	Yes
Flow waveform		Yes	Yes	Yes
Spirometry loops		No	No	Yes
Data output		Yes	Yes	Yes
Parameters				
I:E ratio	2.0:1- 1:5	YES	YES	YES
Frequency	2 - 99 bpm	YES	YES	YES
Set tidal volume	20 -1500 ml	YES	YES	YES
Minute volume	0.3 - 25 lpm	YES	YES	YES
Pressure limit	Adult: 10 - 70 cmH_20 Pediatric: 10- 50 cmH_20	YES	YES	YES

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Model Number		*900 Series*		
		950	**970**	**990**
PEEP	3 -20 cmH_20	YES	YES	YES
Inspiratory pause	0 - 50%	YES	YES	YES
Sigh function	The delivered tidal volume is increased by 10% every 10 breaths	YES	YES	YES
Patient trigger	1 - 15 lpm	YES	YES	YES
Pressure inspired	10- 50 cmH_20	YES	YES	YES
Max inspiratory flow	100 lpm	YES	YES	YES
Support pressure	5 - 30 cmH_20	YES	YES	YES
User Set Alarms				
Pressure high	10 - 70 cmH_20 (equal to pressure limit in volume control or pressure inspired + 25% in pressure control)	YES	YES	YES
Pressure low	5 – 50 cmH_20	YES	YES	YES
MV high	1 - 25 lpm	YES	YES	YES
MV low	0 - 24 lpm	YES	YES	YES
High bpm	3 - 99 bpm	YES	YES	YES
Low bpm	0 - 98 bpm	YES	YES	YES
High oxygen	19 - 110%	YES	YES	YES
Low oxygen	18 - 109%	YES	YES	YES
Apnea		YES	YES	YES
Sensor error		YES	YES	YES
Vent in operative		YES	YES	YES
Inspiratory flow transducer error		YES	YES	YES
Setting error		YES	YES	YES
Peep error		YES	YES	YES
Under pressure		YES	YES	YES
Low supply gas pressure		YES	YES	YES
No charge		YES	YES	YES
Power fail		YES	YES	YES
Battery low		YES	YES	YES
Comms fail		YES	YES	YES
Apnea alarms in bag mode		YES	YES	YES
Sustained pressure		YES	YES	YES
Fresh gas too high		YES	YES	YES

Intended Use: The Blease 900 Series Ventilators are advanced, microprocessor-controlled, pneumatically driven ventilators, which have been designed specifically for the mechanical ventilation of adult and pediatric patients under general anesthesia.

Technology Comparison: The Spacelabs Blease 900 employ the same technological characteristics as the predicate device.

Characteristic	*Predicate Device*	*Proposed Device*
Mechanical Housing Configuration	Integrated into an anesthesia workstation	Stand-alone device.
Ventilation Delivery Subsystem	Pneumatic flow control valve with solenoid driven exhalation valve	Same

Ventilation Delivery Modes	Volume Control; Precision Pressure Control™; Advanced Pressure Support™; SIMV-VC + PSV; SIMV-PC + PSV	Same

Summary of Performance Testing:

Electrical Safety Testing

The Spacelabs Blease 900 was tested for performance in accordance with the following Standard:

- *IEC 60601-1: 2005, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

Test results indicated that the Spacelabs Blease 900 complies with the Standards.

Electromagnetic Compatibility Testing

The Spacelabs Blease 900 was tested for performance in accordance with the following Standard:

- *IEC 60601-1-2: 2007, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.*

Test results indicated that the Spacelabs Blease 900 complies with the Standards.

Performance Testing

The Spacelabs Blease 900 was tested for performance in accordance with internal requirements and the following Standard:

- *ASTM D4169-05, Standard practice for performance testing of shipping containers and systems.*

Test results indicated that the Spacelabs Blease 900 complies with its predetermined specification and with the applicable Standards.

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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 Blease 900. The results of these activities demonstrate that the Spacelabs Blease 900 is safe and effective when used in accordance with its intended use and labeling.

Therefore, the Spacelabs Blease 900 is considered substantially equivalent to the predicate device.

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
C/O Mr. Thomas Kroenke
Principal Consultant
Speed To Market, Inc.
PO Box 3018
Nederland, Colorado 80466

JUN 11 2012

Re: K112729
Trade/Device Name: Spacelabs Blease 900 Series Ventilators
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: June 1, 2012
Received: June 4, 2012

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

Anthony D. Watson, B.S., M.S., M.B.A.
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): K

Device Name: Spacelabs Blease 900 Series Ventilators

Indications for Use: The Blease 900 Series Ventilators are advanced, microprocessor-controlled, pneumatically driven ventilators, which have been designed specifically for the mechanical ventilation of adult and pediatric patients under general anesthesia.

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)

L Schuttler

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

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