510(k) Premarket Notification
Spacelabs Healthcare Ltd.
BleaseSirius Anesthesia Workstation
510(k) Summary

K101850

MAR - 2 2011

Submission Date: 28 June 2010

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 BleaseSirius Anesthesia Workstation

Common Name: Anesthesia Gas Machine

Classification Name: Gas-machine, Anesthesia

Classification Regulation: 21 CFR §868.5160

Product Code: BSZ

Substantially Equivalent Devices:

New Spacelabs Model	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
Spacelabs BleaseSirius Anesthesia Workstation	K051629	Spacelabs Blease Frontline Sirius 2000, 3000

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Device Description:

The Spacelabs BleaseSirius Anesthesia Workstation (BleaseSirius) is an anesthesia workstation that contains all the pneumatic circuitry, controls, monitoring, ancillaries and storage required to control, distribute and mix medical gases and anesthetic agents in order to deliver them to a patient system. It is capable of delivering oxygen, air and nitrous oxide in a controlled manner to various patient breathing circuits with or without the use of mechanical ventilator, and may be used for the delivery of anesthetic vapor by use of a dismountable vaporizer. The Spacelabs BleaseSirius is the latest generation product in a family of anesthesia workstations.

The same breathing circuits used with the predicate device, the Blease Frontline Sirius 2000, 3000 cleared by FDA in 510(k) premarket notification K051629, are used with the Spacelabs BleaseSirius.

Intended Use:

The Spacelabs BleaseSirius Anesthesia Workstation is intended for use in the hospital environment and operating room. It may be used for the delivery of oxygen, air and nitrous oxide in a controlled manner to various patient breathing circuits with or without the use of mechanical ventilator, and may be used for the delivery of anesthetic vapor by use of a dismountable vaporizer.

The device is intended for use only by a suitably qualified physician.

Technology Comparison:

The Spacelabs BleaseSirius Anesthesia Workstation employs the same technological characteristics as the predicate device.

Summary of Performance Testing:

Electrical Safety

The Spacelabs BleaseSirius was tested for patient safety in accordance with applicable Standards.

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

Electromagnetic Compatibility Testing

The Spacelabs BleaseSirius was tested for EMC in accordance with applicable Standards.

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

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Performance Testing	The Spacelabs BleaseSirius was tested for performance in accordance with predetermined specifications and applicable Standards. Test results indicated that the Spacelabs BleaseSirius complies with its predetermined specification and with the applicable Standards.
Software Testing	Software for the Spacelabs BleaseSirius was designed and developed according to a robust software development process, and was rigorously verified and validated. Test results indicated that the Spacelabs BleaseSirius complies with its predetermined specification.
Conclusion	Based upon a comparison of devices and performance testing results, Spacelabs BleaseSirius is 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 Limited
C/O Mr. Thomas Kroenke
Speed to Market, Incorporated
PO Box 3018
Nederland, Colorado 80466

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Re: K101850
Trade/Device Name: Spacelabs BleaseSirius Anesthesia Workstation
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: February 18, 2011
Received: February 22, 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,

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): K101850

Device Name: Spacelabs BleaseSirius Anesthesia Workstation

Indications for Use:

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The device is intended for use only by a suitably qualified physician.

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

510(k) Number: K101850