K113051

MAR 2 2 2012

510(k) Summary

Submission Date:	11 October 2011
Submitter:	Spacelabs Healthcare Ltd. 1 Harforde Court, John Tate Road Hertford, SG13 7NW United Kingdom
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Official Correspondent:	Thomas Kroenke Principal Consultant Speed To Market, Inc. PO Box 3018 Nederland, CO 80466 USA tkroenke@speedtomarket.net +1 (303) 956 4232
Manufacturing Site:	Spacelabs Medical, Inc. 5150 220th Avenue SE Issaquah, WA 98029 USA
Trade Name:	Spacelabs Arkon Anesthesia Workstation
Common Name:	Anesthesia workstation with continuous ventilator
Classification Name:	Ventilator, continuous, facility use; Gas-machine, anesthesia
Classification Regulation:	21 CFR §868.5895; 21 CFR §868.5160
Primary Product Code:	CBK
Secondary Product Code:	BSZ

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

Device Description: The Spacelabs Arkon Anesthesia Workstation (Arkon) 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 a mechanical ventilator, and may be used for the delivery of anesthetic vapor by use of a dismountable vaporizer.

Intended Use: The Spacelabs Arkon 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 Arkon Anesthesia Workstation employs the same technological characteristics as the predicate device.fs

Summary of Performance Testing:

Biocompatibility Verification Patient contact materials within the Arkon and its accessories were verified in accordance with the following standard:

- *ISO 10993-1: 2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.*

Verification results indicated that the materials comply with the standard.

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Software Testing

The Arkon software was designed and developed according to a robust software development process, and was rigorously verified and validated. Software information is provided in accordance with internal requirements and the following standards and guidance documents:

- *FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05;*
- *FDA guidance: Off-the-shelf software use in medical devices, 09 Sep 99; and*
- *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02.*
- *IEC 62304: 2006, Medical device software – Software life cycle processes.*
- *ISO 14971: 2007, Medical devices – Application of risk management to medical devices*

Test results indicate that the Arkon complies with its predetermined specifications and the applicable standards and guidance documents.

Electrical Safety Testing

The Arkon was tested for patient safety in accordance with the following standards:

- *IEC 60601-1: 1988, Am1: 1991, Am2: 1995, Medical Electrical Equipment, Part 1: General Requirements for Safety; and*
- *UL 60601-1: 2006, Medical Electrical Equipment, Part 1: Particular Requirements for Safety.*

Test results indicated that the Arkon complies with the applicable Standards.

Electromagnetic Compatibility Testing

The Arkon was tested for EMC in accordance with the following standard:

- *IEC 60601-1-2: 2007, Medical Electrical Equipment, Part 1: Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility-Requirements and Tests.*

Test results indicated that the Arkon complies with the applicable Standard.

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Performance Testing

The Arkon was tested for performance in accordance with internal requirements and the following standards:

- *IEC 60601-1-6: 2004, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.*
- *IEC 60601-1-8: 2006, Medical electrical equipment – General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.*
- *ASTM F1101-90 (2003) e1, Standard Specification for ventilators intended for use during anesthesia.*
- *CGA C-9: 2004, Standard Color Marking of Compressed Gas Containers for Medical Use.*
- *CGA V-5: 2008, Diameter Index Safety System (Noninterchangeable Low Pressure Connections for Medical Gas Applications).*
- *IEC 60601-2-13: 2003, Am1: 2006, Medical electrical equipment – Particular requirements for the safety and performance of anesthetic systems.*
- *IEC 62366: 2007, Medical devices – Application of usability engineering to medical devices.*
- *ISO 5356-1: 2004, Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets.*
- *ISTA Procedure 1B, Non-simulation integrity performance test procedure – Packaged-products over 150 lb (68 kg).*

Test results indicate that the Arkon complies with its predetermined specifications and the applicable standards.

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of the Arkon. The results of these activities demonstrate that the Arkon is safe and effective when used in accordance with its intended use and labeling.

Therefore, the Arkon 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

MAR 2 2 2012

Spacelabs Healthcare, LTD
C/O Mr. Thomas Kroenke
Principal Consultant
Speed To Market, Inc.
P.O. Box 3018
Nederland, Colorado 80466

Re: K113051
Trade/Device Name: Spacelabs Arkon Anesthesia Workstation
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK, BSZ
Dated: February 23, 2012
Received: February 24, 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 Arkon Anesthesia Workstation

Indications for Use: The Spacelabs Arkon 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.

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 L. Schultheiss

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

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