K121017

510(k) Summary

JUL 13 2012

Submission Date:	21 March 2012
Submitter:	Spacelabs Healthcare 5150 220th Avenue SE Issaquah, WA 98029
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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 Healthcare 5150 220th Avenue SE Issaquah, WA 98029
Trade Name:	Spacelabs Healthcare Capnography Pod (92516)
Common Name:	CO_2 monitor
Classification Name:	Carbon dioxide gas analyzer
Classification Regulation:	21 CFR §868.1400
Product Code:	CCK

Substantially Equivalent Devices:	*New Spacelabs Model*	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
	Spacelabs Healthcare Capnography Pod (92516)	K112173	Spacelabs Multigas Module, Model 92518

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Device Description: The Spacelabs Healthcare Capnography Pod (92516) (CapnoPod) is an easy-to-use modular unit in the Spacelabs Healthcare family of monitors). The CapnoPod is attached to the pod connection on the rear of a Qube Compact Monitor (91390) (Qube). The Qube is then used to control the CapnoPod, and provide the user interface for the CapnoPod.

The CapnoPod is a sidestream analyzer intended to provide a measurement of the following parameters: carbon dioxide (CO_2); and respiratory rate.

The Qube displays information from the CapnoPod and is the user interface for the CapnoPod. The Qube provides a number display for CO_2 and respiratory rate, and a capnograph waveform. The CapnoPod is intended to be used primarily in the operating room environment.

Intended Use: The Spacelabs Healthcare Capnography Pod, Model 92516 (CapnoPod) is intended to provide a means of monitoring carbon dioxide and respiration rate and alert clinical personnel when the concentration moves outside of user-defined limits.

The CapnoPod is intended to be used with and controlled by a Spacelabs Healthcare monitors. The CapnoPod is intended to be used for monitoring adult, pediatric and neonate patients, under the direction of qualified medical personnel.

Technology Comparison: The CapnoPod employs the same technological characteristics as the predicate device.

Characteristic	*Predicate Device*	*Proposed Device*
Parameters	Carbon dioxide (CO_2); oxygen (O_2) and nitrous oxide (N_2O); anesthetic agents including: desflurane, enflurane, halothane, isoflurane, and sevorflurane; respiratory rate; and calculated MAC and age-dependent MAC values.	Carbon dioxide (CO_2); and respiratory rate.
$EtCO_2$	Yes	Same
$FiCO_2$	Yes	Same
Measurement Technology	Infrared Sensor	Same
Sampling Technique	Sidestream	Same
Respiration Rate (RR) Range	4 to 60 breaths per minute (bpm)	1.5 to 150 bpm
RR Accuracy	± 1 bpm	Same

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Summary of Performance Testing:

Electrical Safety

The CapnoPod was tested for performance 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: 2003, Medical electrical equipment – Part 1. General requirements for safety.*

Test results indicated that the CapnoPod complies with the Standards.

Electromagnetic Compatibility (EMC) Testing

The CapnoPod 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 CapnoPod complies with the Standards.

Software Testing

Software device modifications made to the CapnoPod were designed and developed according to a robust software development process, and were rigorously verified and validated.

Software information is provided in accordance with internal documentation 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;*
- *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02;*
- *IEC 60601-1-4: 2000, Medical electrical equipment Medical electrical equipment – Part 1-4: General requirements for safety – Collateral Standard: Programmable electrical medical systems.*

Test results indicate that the CapnoPod complies with its predetermined specification and the Standards and guidance documents.

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Performance Testing

The CapnoPod was tested for performance in accordance with internal documentation and the following Standards:

- *IEC 60601-1-8: 2006, Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems; and*
- *ISO 21647: 2004, Medical electrical equipment – Particular requirements for the basic safety and essential performance of respiratory gas monitors.*

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

Conclusion

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

Therefore, the CapnoPod 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, Incorporated
P.O. Box 3018
Nederland, Colorado 80466

JUL 30 2012

Re: K121017
Trade/Device Name: Spacelabs Healthcare Capnography Pod (92516)
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: June 13, 2012
Received: June 15, 2012

Dear Mr. Kroenke:

This letter corrects our substantially equivalent letter of July 13, 2012.

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 (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 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): K121017

Device Name: Spacelabs Healthcare Capnography Pod (92516)

Indications for Use:

The Spacelabs Healthcare Capnography Pod, Model 92516 (CapnoPod) is intended to provide a means of monitoring carbon dioxide and respiration rate and alert clinical personnel when the concentration moves outside of user-defined limits.

The CapnoPod is intended to be used with and controlled by a Spacelabs Healthcare monitors. The CapnoPod is intended to be used for monitoring adult, pediatric and neonate patients, under the direction of qualified medical personnel.

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: _____