K130192

510(k) Summary

MAR 2 1 2013

Submission Date:	08 January 2013
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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 Capno Module, 92517
Common Name:	CO_2 monitor
Classification Name:	Carbon dioxide gas analyzer
Classification Regulation:	21 CFR §868.1400
Product Code:	CCK

Substantially Equivalent Devices:	*New Model*	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
	Spacelabs Healthcare Capno Module, 92517	K121017	Spacelabs Healthcare Capnography Pod (92516)

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Device Description: The Spacelabs Healthcare Capno Module, 92517 (92517) is an easy-to-use modular unit used with Spacelabs Healthcare Ultraview SL or XPREZZON monitors. The 92517 is inserted into the bay within the monitors, which is then used to control the 92517, and provide the user interface for the 92517.

The 92517 is a sidestream or mainstream analyzer intended to provide a measurement of the following parameters: carbon dioxide (CO_2); and respiratory rate.

The monitor provides a number display for CO_2 and respiratory rate, and a capnograph waveform. The 92517 is intended to be used primarily in the operating room environment.

Intended Use: The Capno Module, 92517 (92517) 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 92517 is intended to be used with and controlled by a Spacelabs Healthcare monitors. The 92517 is intended to be used for monitoring adult, pediatric and neonate patients, under the direction of qualified medical personnel.

Technology Comparison: The 92517 employs the same technological characteristics as the predicate device.

Characteristic	*Predicate Device*	*Proposed Device*
Parameters	Carbon dioxide (CO_2); and respiratory rate.	Same
$EtCO_2$	Yes	Same
$FiCO_2$	Yes	Same
Measurement Technology	Infrared Sensor	Same
Sampling Technique	Sidestream	Sidestream and mainstream

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Summary of Performance Testing:

Electrical Safety

The 92517 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 92517 complies with the Standards.

Electromagnetic Compatibility (EMC) Testing

The 92517 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 92517 complies with the Standards.

Software Testing

Software device modifications made to the 92517 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; and*
- *IEC 62304: 2006, Medical device software – Software life cycle processes.*

Test results indicate that the 92517 complies with its predetermined specification and the Standards and guidance documents.

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Performance Testing

The 92517 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 92517 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 92517. The results of these activities demonstrate that the 92517 is safe and effective when used in accordance with its intended use and labeling.

Therefore, the 92517 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 Center – WO66-G609
Silver Spring, MD 20993-0002

March 21, 2013

Spacelabs Healthcare
C/O Mr. Thomas Kroenke
Principal Consultant
Speed To Market, Incorporated
P.O. Box 3018
NEDERLAND CO 80466

Re: K130112
Trade/Device Name: Spacelabs Healthcare Capno Module, 92517
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: February 14, 2013
Received: February 22, 2013

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,

Kwame O. Ulmer for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, 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 130112

Device Name: Spacelabs Healthcare Capno Module, 92517

Indications for Use: The Capno Module, 92517 (92517) 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 92517 is intended to be used with and controlled by a Spacelabs Healthcare monitors. The 92517 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)

Lester W. Schultheis Jr
2013.03.12 12:11:55 -04'00'

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

510(k) Number: K130112