K120616

MAR 2 9 2012

# *510(k) Premarket Notification*
# *Spacelabs Healthcare*
# *Qube Compact Monitor (91390)*
# *510(k) Summary*

| | |
|---|---|
| ***Submission Date:*** | 24 February 2012 |
| ***Submitter:*** | Spacelabs Medical, Inc.<br>5150 220th Avenue SE<br>Issaquah, WA 98029 USA |
| ***Submitter Contact:*** | Mr. Al Van Houdt<br>Spacelabs Medical, Inc.<br>Phone: +1 (425) 657-7200, ext 5970<br>Fax: +1 (425) 657-7210<br>Email: al.vanhoudt@spacelabs.com |
| ***Official Contact:*** | Thomas Kroenke<br>Principal Consultant<br>Speed To Market, Inc.<br>PO Box 3018<br>Nederland, CO 80466 USA<br>tkroenke@speedtomarket.net<br>303 956 4232 |
| ***Manufacturing Site:*** | Spacelabs Medical, Inc.<br>5150 220th Avenue SE<br>Issaquah, WA 98029 USA |
| ***Trade Name:*** | Spacelabs Healthcare Qube Compact Monitor (91390) |
| ***Common Name:*** | Monitor, physiological, patient (with arrhythmia detection or alarms) |
| ***Classification Name:*** | Monitor, physiological, patient (with arrhythmia detection or alarms) |
| ***Classification Regulation:*** | 21 CFR §870.1025 |
| ***Product Code:*** | MHX |

| ***Substantially Equivalent Devices:*** | *New Spacelabs Model* | *Predicate 510(k) Number* | *Predicate Manufacturer / Model* |
|---|---|---|---|
| | Spacelabs Healthcare Qube Compact Monitor (91390) | K102422 | Spacelabs Medical Patient Monitors, Models 91367, 91369, 91370, 91388 |

K120616

# *510(k) Premarket Notification*
# *Spacelabs Healthcare*
# *Qube Compact Monitor (91390)*
# *510(k) Summary*

***Device Description:*** The Spacelabs Spacelabs Healthcare Qube Compact Monitor (91390) (Qube) is a component of the Spacelabs Medical Patient Monitoring System. The monitor accepts and displays parameter information, waveform and numeric data, and alarm conditions including arrhythmia information received from the same family of modules as its predicate, the Spacelabs Medical Model 91370 Patient Monitor.

***Intended Use:*** The Spacelabs Healthcare Qube Compact Monitor (91390), functioning as either bedside or central monitors; passively displays data generated by Spacelabs Heatthcare parameter modules, Flexports interfaces, and other SDLC based products in the form of waveform and numeric displays, trends and alarms. Key monitored parameters available on the Model 91390 when employing the Spacelabs Command Module, consist of ECG, respiration, invasive and noninvasive blood pressure, $SpO_2$, temperature and cardiac output. Additional parameters and interfaces to other systems are also available depending on the parameter modules employed.

The Qube is intended to alert the user to alarm conditions that are reported by Spacelabs Healthcare parameter modules and/or other physiologic monitors via Flexport interfaces. These devices determine a) when an alarm condition is violated; b) the alarm priority (i.e. high, medium or low); c) alarm limits; and d) when to initiate and terminate alarm notifications. The patient monitors are also capable of displaying alarm conditions on other monitors that are on the network through the Alarm Watch feature.

The Qube may also function as a generic display or computer terminal. As a generic display or terminal, the patient monitors allow networkbased applications to open windows and display information on other networked monitors.

The Qube is also designed to communicate with a variety of external devices such as displays, network devices, serial devices, user input devices, audio systems, and local/remote recorders.

The Qube is intended for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in proper use of the equipment in a hospital environment.

K120616

# *510(k) Premarket Notification*
# *Spacelabs Healthcare*
# *Qube Compact Monitor (91390)*
# *510(k) Summary*

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

| *Characteristic* | *Predicate Device* | *Proposed Device* |
|---|---|---|
| *Bedside, Transport or Central Station* | Bedside/ Transport | Bedside/ Transport / Central Station |
| *Maximum Parameter Capacity* | 18 | Same |
| *Number of Internal Module Slots* | 1 | Same |
| *Maximum Number of Remote Module Housings Slots* | 1 | Same |
| *User Interface Methods* | Touchscreen, Keyboard, Mouse, Remote Keyboard | Same |
| *Bedside Monitor (Visible waveforms)* | 4 – 6 | Same |
| *Display Technology* | Color TFT-LCD | Same |

***Summary of Performance Testing:***

***Software Validation*** The Qube software was tested for performance in accordance with internal requirements and the following Standard:

- *IEC 60601-1-4: 1996, Am1: 1999, Medical electrical equipment, Part 1-4 – Collateral Standard: Programmable electrical medical systems.*

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

***Electrical Safety Testing*** The Qube was tested for performance in accordance with the following Standard:

- *IEC 60601-1: 1988, Am1: 1991, and Am2: 1995, Medical electrical equipment, Part 1: Particular requirements for safety.*

Test results indicated that the Qube complies with the Standards.

# *510(k) Premarket Notification*
# *Spacelabs Healthcare*
# *Qube Compact Monitor (91390)*
# *510(k) Summary*

***Electromagnetic Compatibility Testing***

The Qube 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 Qube complies with the Standards.

***Performance Testing***

The Qube was tested for performance in accordance with internal requirements and the following Standard:

- *IEC 60601-1-6: 2010, 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.*
- *IEC 62366: 2007, Medical devices – Application of usability engineering to medical devices.*
- *ISTA Procedure 1A, Non-simulation integrity performance test procedure – Packaged-products under 150 lb (68 kg).*

Test results indicated that the Qube 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 device modifications made to the Qube. The results of these activities demonstrate that the Qube is safe and effective when used in accordance with its intended use and labeling.

Therefore, the Qube 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 9 2012

Spacelabs Medical, Inc.
c/o Mr. Thomas Kroenke
Speed To Market, Inc.
P.O. Box 3018
Nederland, CO 80466

Re: K120616
Trade/Device Name: Spacelabs Healthcare Qube Compact Monitor (91390)
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II (two)
Product Codes: MHX
Dated: February 24, 2012
Received: February 29, 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.

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.

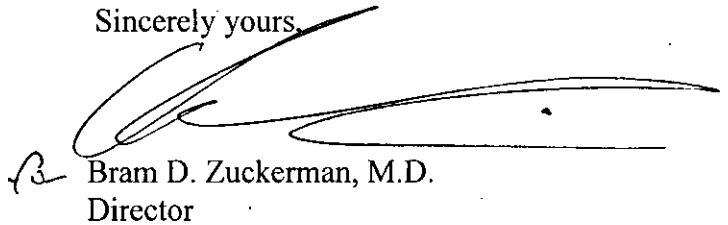
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 120616

Device Name: Spacelabs Healthcare Qube Compact Monitor (91390)

Indications for Use:

The Spacelabs Healthcare Qube Compact Monitor (91390), functioning as either bedside or central monitors; passively displays data generated by Spacelabs Heatthcare parameter modules, Flexports interfaces, and other SDLC based products in the form of waveform and numeric displays, trends and alarms. Key monitored parameters available on the Model 91390 when employing the Spacelabs Command Module, consist of ECG, respiration, invasive and noninvasive blood pressure, $SpO_2$, temperature and cardiac output. Additional parameters and interfaces to other systems are also available depending on the parameter modules employed.

The Qube is intended to alert the user to alarm conditions that are reported by Spacelabs Healthcare parameter modules and/or other physiologic monitors via Flexport interfaces. These devices determine a) when an alarm condition is violated; b) the alarm priority (i.e. high, medium or low); c) alarm limits; and d) when to initiate and terminate alarm notifications. The patient monitors are also capable of displaying alarm conditions on other monitors that are on the network through the Alarm Watch feature.

The Qube may also function as a generic display or computer terminal. As a generic display or terminal, the patient monitors allow networkbased applications to open windows and display information on other networked monitors.

The Qube is also designed to communicate with a variety of external devices such as displays, network devices, serial devices, user input devices, audio systems, and local/remote recorders.

The Qube is intended for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in proper use of the equipment in a hospital environment.

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 Cardiovascular Devices**

**510(k) Number** K120616