**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

September 9, 2014

Spacelabs Healthcare
% Thomas Kroenke
Speed To Market, Inc.
P.O. Box 3018
Nederland, CO 80466 US

Re: K141156
Trade/Device Name: Spacelabs Healthcare Telemetry Receiver
Regulation Number: 21 CFR 870.1025
Regulation Name: Monitor, Physiological, Patient (with Arrhythmia Detection Or Alarms)
Regulatory Class: Class II
Product Code: MHX, DSI, MLD, MSX
Dated: June 31, 2014
Received: August 4, 2014

Dear Thomas 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

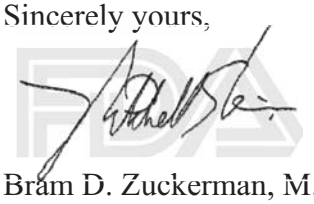
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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 contact 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 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): | K141156 |
| Device Name: | Spacelabs Healthcare Telemetry Receiver, Model 96280 |
| Indications for Use: | The Spacelabs Healthcare Telemetry Receiver, Model 96280, is intended to provide the Spacelabs Healthcare monitoring system with adult, pediatric and neonatal patient data of patients connected to Spacelabs Healthcare telemetry transmitters. Data includes physiological waveforms and calculations, cardiac arrhythmia and ST data, and patient demographic information to monitor adequacy of treatment or to exclude causes of symptoms. |

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)

# *510(k) Summary*

| | |
|---|---|
| ***Submission Date:*** | 02 May 2014 |
| ***Submitter:*** | Spacelabs Healthcare<br>35301 SE Center St<br>Snoqualmie, WA 98065 |
| ***Submitter Contact:*** | Mr. Al Van Houdt<br>Spacelabs Healthcare<br>Phone: +1 (425) 363- 5970<br>Fax: +1 (425) 363-5762<br>Email: al.vanhoudt@spacelabs.com |
| ***Application Correspondent:*** | 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 Healthcare<br>35301 SE Center St<br>Snoqualmie, WA 98065 |
| ***Trade Name:*** | Spacelabs Healthcare Telemetry Receiver, Model 96280 |
| ***Common Name:*** | Telemetry Receiver |
| ***Classification Name:*** | Monitor, Physiological, Patient (With Arrhythmia Detection or Alarms); |
| ***Primary Classification Regulation:*** | 21 CFR §870.1025 |
| ***Primary Product Code:*** | MHX |
| ***Secondary Classification Regulation:*** | 21 CFR §870.1025; 21 CFR §870.2300 |
| ***Secondary Product Code:*** | DSI; MLD; MSX |

# *510(k) Summary*

K141156

| ***Substantially Equivalent Devices:*** | *New Spacelabs Model* | *Predicate 510(k) Number* | *Predicate Manufacturer / Model* |
|---|---|---|---|
| | Spacelabs Healthcare Telemetry Receiver, Model 96280 | K925510 | Spacelabs Medical, Inc. Model 90478 and 90479 Telemetry Receiver Module and Housing |

***Device Description:*** The Spacelabs Healthcare (Spacelabs) Telemetry Receiver, Model 96280, (ETR) is a new version of a currently marketed Spacelabs product. The Spacelabs ETR offers receipt and analysis of patient data for those patients connected to a Spacelabs Healthcare telemetry transmitter.

The Spacelabs ETR provides for data communication using the TCP/IP network protocol employed in the Xhibit Central Station, Model 96102, (Xhibit) (K122146) network of hardwired and/or ETR monitored patients.

Xhibit is the primary alarming device for the ETR telemetry receiver system.

***Intended Use:*** The Spacelabs Healthcare Telemetry Receiver, Model 96280, is intended to provide the Spacelabs Healthcare monitoring system with adult, pediatric and neonatal patient data of patients connected to Spacelabs Healthcare telemetry transmitters. Data includes physiological waveforms and calculations, cardiac arrhythmia and ST data, and patient demographic information to monitor adequacy of treatment or to exclude causes of symptoms.

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

| *Characteristic* | *Predicate Device* | *Proposed Device* |
|---|---|---|
| *Number of Patients per Receiver Channel* | 1 | Same |
| *Patients per Receiver Housing* | Up to 8 | Up to 16 |
| *Receivers Connected to Central Station* | Two (2)<br>(Ultraview can display 16 patients) | Three (3)<br>(Xhibit can display 48 patients) |
| *Number of Displays / Patients per Display* | One (1) display / 16 patients per display | Three (3) displays / 16 patients per display |
| *Receiver Capability* | ECG, SpO2, NIBP | Same |
| *ECG Analysis in Receiver* | Yes | Same |
| *Prioritized Alarms* | Yes | Same |

# *510(k) Summary*

***Summary of Performance Testing:***

*Software*

The Spacelabs ETR contains MAJOR level of concern software. 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;*
- *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02;*
- *FDA guidance: Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm, 28 October 2003;*
- *FDA guidance: Cybersecurity for networked medical devices containing off-the-shelf (OTS) software, 14 January 2005; and*
- *IEC 62304: 2006, Medical device software – Software life cycle processes.*

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

*Electrical Safety*

The Spacelabs ETR was tested for performance in accordance with the following standard:

- *IEC 60601-1: 2005, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

Test results indicate that the Spacelabs ETR complies with the applicable standards.

*Electromagnetic Compatibility*

The Spacelabs ETR 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 indicate that the Spacelabs ETR complies with the applicable standards.

# *510(k) Summary*

*Performance Testing – Bench*

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

- *ANSI/AAMI EC-57: 2012, Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms.*
- *IEC 60601-1-8 2006, Am1: 2012, Medical electrical equipment – General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.*
- *IEC 60601-2-27: 2011, Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment.*
- *IEC 80601-2-61: 2011, Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.*
- *IEC 62366: 2007, Medical devices – Application of usability engineering to medical devices.*

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

Therefore, the Spacelabs ETR is considered substantially equivalent to the predicate device.