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

April 1, 2016

Spacelabs Healthcare Ltd.
% Thomas Kroenke
Principal Consultant, Speed To Market, Inc.
PO Box 3018
Nederland, Colorado 80466

Re: K152881
Trade/Device Name: Sentinel Cardiology Information Management System
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DXH
Dated: February 26, 2016
Received: February 29, 2016

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.

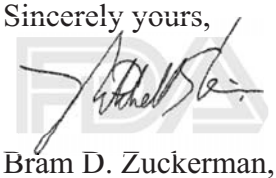
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 Industry and Consumer Education 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 Industry and Consumer Education 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152881

Device Name
Spacelabs Healthcare Ltd. Sentinel Cardiology Information Management System

Indications for Use *(Describe)*

The Sentinel Cardiology Information Management System is intended to connect to supported medical devices and analyzers in order to download, store, access and manage cardiovascular information and to manage patient and facility information.

The Sentinel Cardiology Information Management System provides download and storage of data from supported Holter recorders and feeds this data to separate and optional Holter analyzers. The completed reports are stored back in Sentinel.

The Sentinel Cardiology Information Management System facilitates presenting, analyzing, reviewing cardiovascular information, including automatic interpretation of 12 lead ECG and stores the finished reports. The automatic interpretation of 12-lead ECG is not suitable for neonates.

Sentinel supports importing reports from external systems and provides an HL7 interface to external systems.
The Sentinel Cardiology Information Management System is intended to be used by a trained user and as an aid to a medical professional in hospital or primary care environment.

The Sentinel Cardiology Information Management System is not intended for patient monitoring.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submission Date:	25 February 2016
Submitter:	Spacelabs Healthcare Ltd. 1 Harforde Court John Tate Road Hertford United Kingdom SG13 7NW
Submitter Contact:	Mr. Al Van Houdt Spacelabs Healthcare Phone: +1 (425) 363- 5970 Fax: +1 (425) 363-5762 Email: al.vanhoudt@spacelabs.com
Application Correspondent:	Thomas Kroenke Speed To Market, Inc. PO Box 3018 Nederland, CO 80466 USA tkroenke@speedtomarket.net 303 956 4232
Manufacturing Site:	Spacelabs Healthcare 35301 SE Center Street Snoqualmie, WA 98065
Trade Name:	Sentinel Cardiology Information Management System
Common Name:	Programmable Diagnostic Computer
Primary Classification Name:	Programmable Diagnostic Computer
Primary Classification Regulation:	21 CFR §870.1425
Primary Product Code:	DQK
Secondary Classification Name:	Transmitters and Receivers, Electrocardiograph, Telephone
Secondary Classification Regulation:	21 CFR §870.2920
Secondary Product Code:	DXH

510(k) Summary

Substantially Equivalent Devices:	*New Spacelabs Model*	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
	Sentinel Cardiology Information Management System	K062397	DelMar Reynalds Medical Ltd. (now part of Spacelabs Healthcard Ltd.) / Sentinel
		K130155	GE Medical Systems Information Technologies / MUSE Cardiology Information System

Device Description:

The Spacelabs Healthcare Ltd. (Spacelabs) Sentinel Cardiology Information Management System (Spacelabs) is a stand-alone software product which can capture, store, access and manage electrocardiograph (ECG), ambulatory blood pressure (ABP), stress test, ergospirometry, spirometry, event and plethysmography data with Holter analyses and reports, together with the corresponding patient information. Sentinel can be used as a single stand-alone installation, or as part of a multi-user network. Sentinel may be used for recording and reviewing of ECG of adults and pediatrics in a clinical environment inside and outside of hospitals.

Intended Use:

The Sentinel Cardiology Information Management System is intended to connect to supported medical devices and analyzers in order to download, store, access and manage cardiovascular information and to manage patient and facility information.

The Sentinel Cardiology Information Management System provides download and storage of data from supported Holter recorders and feeds this data to separate and optional Holter analyzers. The completed reports are stored back in Sentinel.

The Sentinel Cardiology Information Management System facilitates presenting, analyzing, reviewing cardiovascular information, including automatic interpretation of 12 lead ECG and stores the finished reports. The automatic interpretation of 12-lead ECG is not suitable for neonates.

Sentinel supports importing reports from external systems and provides an HL7 interface to external systems.

The Sentinel Cardiology Information Management System is intended to be used by a trained user and as an aid to a medical professional in hospital or primary care environment.

The Sentinel Cardiology Information Management System is not intended for patient monitoring.

510(k) Summary

Technology Comparison:

The Spacelabs Sentinel Cardiology Information Management System employs the same technological characteristics as the predicate device.

Characteristic	***GE Medical Systems MUSE***	***DelMar Reynalds Medical Ltd. Sentinel***	***Proposed Device***
Acquisition and Analysis	All compatible devices • ECG measurements • View ECG waveforms • Print ECG waveforms • Edit interpretation • Serial presentation GE devices • ECG interpretation - Marquette 12SL • Serial comparison • 15 lead adult/pediatric • Right ventricular involvement ECG interpretation Third party devices different than above • ECG interpretation – Vendor specific	ABP: TrackerNIBP2, P6, 90207, 90217 • Acquire test • Edit test • Print test • View test Holter: Lifecard CF, Aria • View ECG waveforms • Print ECG waveforms • Edit interpretation 12 Lead: CD12-Serial, CardioCollect • ECG interpretation • View ECG waveforms • Print ECG waveforms • Edit interpretation Carts: Voyager, GE-Mac 5000, GE-Mac 5500, Philips Pagewriter, CarioCollect • View ECG waveforms • Print ECG waveforms • Edit interpretation	ABP: TrackerNIBP2, 90207, 90217, 90217A, 90227 • Acquire test • Edit test • Print test • Review test • Serial presentation Holter, Lifecard CF, Aria. EVO • Review ECG waveforms • Print ECG waveforms • Edit interpretation 12-Lead: CD12-Serial, CD12-USB • ECG interpretation • View ECG waveforms • Print ECG waveforms • Edit interpretation • Serial presentation Carts: Voyager, GE-Mac 5000, Philips Pagewriter • Review ECG waveforms • Print ECG waveforms • Edit interpretation Third party devices different than above • ECG interpretation – Vendor specific
Modalities	• 12 lead resting ECG • Bedside 12 lead ECG • Defibrillators	• Ambulatory BP • 12 lead ECG: Resting • Holter • Stress	• Ambulatory BP • 12 lead ECG: Resting and Rhythm • Holter • Stress • Event

510(k) Summary

Characteristic	*GE Medical Systems MUSE*	*DelMar Reynalds Medical Ltd. Sentinel*	*Proposed Device*
Arrhythmia Analysis	• Marquette 12SL ECG analysis	• Glasgow ECG analysis for 12 lead ECG • HES analysis for stress tests	• Glasgow ECG analysis for 12 lead ECG • HES analysis for stress tests

Summary of Performance Testing:

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

- *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: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, 02 Oct 14; and*
- *IEC 62304: 2006, Medical device software – Software life cycle processes.*

Test results indicated that Spacelabs Sentinel complies with predetermined specifications and the applicable standard.

Electrical Safety

Spacelabs Sentinel is a software product only, and designed to comply with the applicable requirements of:

- *IEC 60601-1: 2005, Am1: 2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

Verification results indicated that Spacelabs Sentinel complies with the applicable requirements of the standard.

510(k) Summary

Performance Testing – Bench

Spacelabs Sentinel was tested in accordance with:

- *IEC 60601-1-6: 2010, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance -- Collateral standard: Usability;*
- *IEC 60601-2-25: 2011, Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs;*
- *IEC 80601-2-30: 2013, Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers; and*
- *IEC 62366: 2006, Am1: 2014, Medical devices - Application of usability engineering to medical devices.*
- Test results indicated that Spacelabs Sentinel complies with predetermined specifications and the applicable standards.

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of Spacelabs Sentinel. The results of these activities demonstrate that Spacelabs Sentinel is as safe, as effective, and performs as well as or better than the predicate device.

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