March 26, 2021

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

Re: K201921
Trade/Device Name: Spacelabs Lifescreen PRO Analyzer
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: February 19, 2021
Received: February 23, 2021

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer Shih Kozen
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201921

Device Name
Spacelabs Lifescreen PRO Analyzer

Indications for Use *(Describe)*
The Spacelabs Lifescreen PRO Analyzer (Model 98800 Analyzer) is intended to be used to analyze recordings of ambulatory electrocardiograms made on compatible ECG recorders. Lifescreen PRO is capable of analyzing the ECG, detecting certain arrhythmias, allowing the user to view and edit analysis results, correlating symptomatic patient events and construct a report for use by Physicians / Cardiologists.

Lifescreen PRO can be used as a triage tool for assessment of ambulatory ECG from supported devices; supporting selection and export of ECG segments for more detailed analysis in the Spacelabs Pathfinder SL Analyzer.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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
(in accordance with 21 CFR 807.92)

Submission Date:	02 July 2020
Submitter:	Spacelabs Healthcare Ltd. Unit B, Foxholes Centre John Tate Road Hertford Hertfordshire SG13 7DT United Kingdom
Submitter Correspondent	Mr. Roger Moldon Phone: +011 44-1992-507730 Email: roger.moldon@spacelabs.com
Application Correspondent:	Thomas Kroenke Principal Consultant Speed To Market, Inc. PO Box 3018 Nederland, CO 80466 USA tkroenke@speedtomarket.net +1 (303) 956 4232
Manufacturing Site:	Spacelabs Healthcare Ltd. Unit B, Foxholes Centre John Tate Road Hertford Hertfordshire SG13 7DT United Kingdom
Trade Name:	Spacelabs Lifescreen PRO Analyzer
Common and Classification Name:	Computer, Diagnostic, Programmable
Classification Regulation:	21 CFR §870.1425
Product Code:	DQK

Substantially Equivalent Devices:	*New Spacelabs Model*	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
	Spacelabs Lifescreen PRO Analyzer	K110001	Spacelabs Pathfinder SL

510(k) Summary
(in accordance with 21 CFR 807.92)

Device Description: The Spacelabs Lifescreen PRO Analyzer is a rapid analysis software product that can be used to analyze electrocardiology (ECG) recordings of up to 30 days in duration from Spacelabs Healthcare's range of Ambulatory ECG recorders. The ECG recordings are downloaded into the Sentinel Cardiology Information Management System (Sentinel), cleared by FDA in 510(k) submission K152881, imported into Lifescreen PRO, and then analyzed.

Lifescreen PRO is designed to provide a rapid analysis of the detection and reporting of major arrhythmic events and patient reported symptomatic events including AF, Pause, VT, V-Run (>3 beats), Trigeminy and Bigeminy, SVT, SV-Run, and Bradycardia.

Individual normal, ventricular, and supraventricular beat burdens are presented as a percentage of the total beat counts.

No automated algorithm for arrhythmia detection offers 100% sensitivity and accuracy for the detection of arrhythmia events. Laboratory testing and clinical studies have shown that scanning and a review of analyzed results by a trained user provides the highest degree of report accuracy. Following analysis, the report should be reviewed by a physician prior to initiating or changing patient treatment.

ECG data with a lot of noise, which can result from poor hook-up and/or poor-quality electrodes, can result in beat misclassification. The algorithm monitors the ECG quality throughout and will inhibit analysis during periods of noise; the inhibited analysis is clearly shown in grey. This allows the user to review the inhibited areas to ensure that significant events have not been missed.

Various tools are provided in Lifescreen PRO to allow the trained user to quickly view the full disclosure ECG, add, delete, or reclassify events and beats, or artefact periods of noisy ECG. Where more detailed analysis is required, Lifescreen PRO also has the ability to export sections of a recording up to 7 days in duration into the Sentinel Cardiology Information Management System for further analysis using the Pathfinder SL analysis system.

510(k) Summary
(in accordance with 21 CFR 807.92)

Intended Use:

The Spacelabs Lifescreen PRO Analyzer (Model 98800 Analyzer) is intended to be used to analyze recordings of ambulatory electrocardiograms made on compatible ECG recorders. Lifescreen PRO is capable of analyzing the ECG, detecting certain arrhythmias, allowing the user to view and edit analysis results, correlating symptomatic patient events and construct a report for use by Physicians / Cardiologists.

Lifescreen PRO can be used as a triage tool for assessment of ambulatory ECG from supported devices; supporting selection and export of ECG segments for more detailed analysis in the Spacelabs Pathfinder SL Analyzer.

Technology Comparison:

The Lifescreen PRO employs the same technological characteristics as the predicate device.

Characteristic	***Spacelabs Healthcare Ltd. Pathfinder SL (K110001)***	***Spacelabs Healthcare Ltd. Lifescreen PRO Analyzer***
Intended Use	The Spacelabs Pathfinder SL Holter Analyzer is intended to be used to analyze recordings of ambulatory electrocardiograms made on compatible Holter recorders. It is capable of detecting certain abnormal arrhythmias, and allows the operator to view and edit the ECG and the analysis results, and construct a report for physician use.	The Spacelabs Lifescreen PRO Analyzer (Model 98800 Analyzer) is intended to be used to analyze recordings of ambulatory electrocardiograms made on compatible ECG recorders. Lifescreen PRO is capable of analyzing the ECG, detecting certain arrhythmias, allowing the user to view and edit analysis results, correlating symptomatic patient events and construct a report for use by Physicians / Cardiologists. Lifescreen PRO can be used as a triage tool for assessment of ambulatory ECG from supported devices; supporting selection and export of ECG segments for more detailed analysis in the Spacelabs Pathfinder SL Analyzer.
Operating Principle	The general operating principle is that the analyzer displays the ECG waveform associated with an ECG recording. The analyzer can be setup to identify and highlight certain types of beats, events or arrhythmias. The operator can review or revised the classifications, make measurements on the ECG waveforms and then collate associated information to generate a report which is intended for review by a physician to aid diagnosis.	Same.

Technology Comparison (cont):

Characteristic	***Spacelabs Healthcare Ltd. Pathfinder SL (K110001)***	***Spacelabs Healthcare Ltd. Lifescreen PRO Analyzer***
Compatibility with ECG Recorders	Compatible with the following Spacelabs devices: • Aria; • Lifecard CF; • Lifecard 12; and • Evo.	Compatible with the following Spacelabs devices: • Lifecard CF; and • Evo.
Compatibility with Databases	Pathfinder SL must be used in conjunction with Spacelabs Sentinel CIMS database which can be one of many SQL Server variants.	Same.
Reports	User customization of report formats.	Same.
Analysis of ECG recordings	Supports analysis and reporting of ECG recordings up to 7 days.	Supports analysis and reporting of ECG recordings up to 30 days.
Sleep Apnea	Integrated the detection and highlighting of possible periods of sleep apnea within the recording.	Not applicable.

510(k) Summary
(in accordance with 21 CFR 807.92)

Summary of Performance Testing:

Software

The Lifescreen PRO 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 guidance documents and Standards:

- *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, 27 Sep 19.*
- *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02.*
- *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, 02 Oct 14.*
- *Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices, 06 Sep 17.*
- *IEC 62304: 2006, Am1:2015, Medical device software – Software life-cycle processes.*
- *IEC 82304-1: 2016, Health Software – Part 1: General requirements for product safety*

Test results indicate that the Lifescreen PRO complies with its predetermined specifications, guidance documents and Standards.

Summary of Performance Testing (continued):

Performance Testing – Bench

The Lifescreen PRO was tested for performance in accordance with internal requirements, applicable Standards, and guidance document.

- *IEC 60601-2-47: 2012, Medical electrical equipment – Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems*
- *IEC 62366-1: 2015, Medical devices – Application of usability engineering to medical devices.*
- *Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices, 06 Sep 17.*

Test results indicated that the Lifescreen PRO complies with internal requirements, applicable Standards, and the guidance document.

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of the Lifescreen PRO. The results of these activities demonstrate that the Lifescreen PRO is as safe, as effective, and performs as well as the predicate device when used in accordance with its intended use and labeling.

Therefore, the Lifescreen PRO is considered substantially equivalent to the predicate device.