November 22, 2021

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

Re: K211651
Trade/Device Name: Eclipse PRO
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: MWJ
Dated: May 27, 2021
Received: May 28, 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,

for

Jennifer Shih Kozen
External Heart Rhythm and Rate Team
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)*
K211651

Device Name
Spacelabs Eclipse PRO Model 98700

Indications for Use *(Describe)*
The Spacelabs Model 98700 is a portable non-invasive Holter recorder intended to record the patient's ambulatory electrocardiogram. The device is intended to be used by either pediatric or adult patients in either a clinical setting or at home. The device does no cardiac analysis and is used with a Holter Analysis System.

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

Submission Date:	20 October 2021
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, Inc. 35301 SE Center Street Snoqualmie, WA 98065 USA
Trade Name:	Eclipse PRO Model 98700
Common and Classification Name:	Electrocardiograph, Ambulatory (Without Analysis)
Classification Regulation:	21 CFR §870.2800
Product Code:	MWJ

Substantially Equivalent Devices:	*New Spacelabs Model*	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
	Eclipse PRO Model 98700	K011837	Reynolds Medical Ltd. Lifecard CF 7 Day

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

Device Description: The Eclipse PRO Model 98700 (Eclipse PRO) is an ambulatory electrocardiograph (ECG) recorder capable of providing a true 12-channel recording for up to 72 hours or a 3-lead recording for up to 14 days. It is connected to the patient using Eclipse PRO-specific 3, 4, or 10 lead wire cables with the recorder located in a pouch on a lanyard.

The Eclipse PRO has a large, color display which allows the user to view recorder status, configure the recorder and to view ECG lead application.

It has an internal, fast-charge, long-life, rechargeable lithium-ion battery, which is charged when connected by a cable between the USB port of a personal computer (PC) or a USB charger, and the recorder's USB-C connector.

Two (2) arrow keys on the front of the Eclipse PRO are used to navigate and select options in the recorder's menu or as a patient event button when the patient desires to indicate symptomatic episodes in the recording.

The Eclipse PRO is fully sealed and waterproof.

Patient cables are attached to the Eclipse PRO using the USB connector on the bottom of the housing and protective cable retention loop.

Patient data from the Eclipse PRO is downloaded to a PC upon which the Spacelabs Sentinel Cardiology Information Management System (Sentinel), cleared in 510(k) submission K152881, has been installed. This allows the clinician to download, view, and analyze patient data from the Eclipse PRO, and create reports. Further analysis of these patient data can be performed by using Spacelabs Pathfinder SL Holter Analyzer (cleared in 510(k) submission K110001) and/or Spacelabs Lifescreen PRO Analyzer (cleared in 510(k) submission K201921).

Finally, a non-medical device mobile phone app is available for patient use as an electronic note taking option in lieu of a manual, written patient diary.

Intended Use: The Spacelabs Model 98700 is a portable non-invasive Holter recorder intended to record the patient's ambulatory electrocardiogram. The device is intended to be used by either pediatric or adult patients in either a clinical setting or at home. The device does no cardiac analysis and is used with a Holter Analysis System.

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

Technology Comparison:

The Spacelabs Healthcare (Spacelabs) Eclipse PRO Model 98700 (Eclipse PRO) employs the same technological characteristics as the predicate device.

Characteristic	*Reynolds Medical Ltd.* *Lifecard CF 7 Day* *(K011837)*	*Spacelabs Healthcare Ltd.* *Eclipse PRO Model 98700* *(Proposed Device)*
Intended Use	The Reynolds Lifecard CF 7-Day Holter recorder (Lifecard CF) is a modification of the Reynolds Lifecard CF Holter Recorder, K001025. It is indicated when it is desired to record the patient's ambulatory electrocardiogram. It is a portable Holter recorder designed to record the patient's ambulatory electrocardiogram for up to seven days.	The Spacelabs Model 98700 is a portable non-invasive Holter recorder intended to record the patient's ambulatory electrocardiogram. The device is intended to be used by either pediatric or adult patients in either a clinical setting or at home. The device does no cardiac analysis and is used with a Holter Analysis System.
Software Information Management and Analyzer Compatibility	The Eclipse PRO is compatible with: • Spacelabs Sentinel Cardiology Information Management System (cleared in K152881). • Spacelabs Pathfinder SL Holter Analyzer (cleared in K110001) • Spacelabs Lifescreen PRO Analyzer (cleared in K201921).	Same.
Channels	1, 2, or 3 channels	3 or 12 channels
Leads	3, 4, and 6 leads	3 leads, 4 leads, and 10 IEC or AHA leads
Recording Duration	Up to 24 hours recording x channels Up to 7 days recording x channels	Up to 3 days recording 12 channels Up to 14 days recording 3 channels
Data Transfer Method between Recorder and Analysis Software	Removable CompactFlash Association (Type 1) card	USB cable
Media Type	Removable CompactFlash Association (Type 1) card	Internal memory

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

Technology Comparison (continued):

Characteristic	*Reynolds Medical Ltd.* *Lifecard CF 7 Day* *(K011837)*	*Spacelabs Healthcare Ltd.* *Eclipse PRO Model 98700* *(Proposed Device)*
Data Stored	Full disclosure ECG, with pacing and patient event markers Recording date and time Patient name and record number (Pathfinder systems) Encrypted patient record file (CardioNavigator) 8 second voice recording Recorder serial number	Full disclosure ECG, with pacing and patient event markers. Recording date and time Patient name and record number (only if permitted by user) Recorder serial number.
Pacemaker Detection	Yes	Same.
Power Source	Battery, rechargeable or disposable	Battery, rechargeable

Summary of Performance Testing:

Shelf-Life

The Eclipse PRO and it's accessories do not have a shelf life.

Biocompatibility

The patient-contact materials in the Eclipse PRO and accessories were tested for biocompatibility compliance in accordance with the following Standard and guidance document:

- *ISO 10993-1: 2009, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process.*
- *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process," 04 Sep 20.*

Test results indicated that the patient-contact materials in the Eclipse PRO and accessories comply with the applicable Standard and guidance document.

Summary of Performance Testing (continued):

Software

The Eclipse PRO 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 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.*
- *Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) software, 14 Jan 05.*
- *Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices, 06 Sep 17.*
- *IEC 62304: 2015, Medical device software – Software life-cycle processes.*

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

Electrical Safety

The Eclipse PRO was tested for patient safety in accordance with the following Standards:

- *IEC 60601-1: 2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*
- *IEC 60601-1-11: 2015, Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.*

Test results indicated that the Eclipse PRO complies with the applicable Standards.

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

Summary of Performance Testing (continued):

Electromagnetic Compatibility

The Eclipse PRO was tested for EMC in accordance with the following Standard:

- *IEC 60601-1-2: 2014, Medical Electrical Equipment, Part 1: Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility-Requirements and Tests.*

Test results indicated that the Eclipse PRO complies with the applicable Standard.

Performance Testing – Bench

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

- *IEC 60601-1-6: 2013, Medical electrical equipment: General requirements for basic safety and essential performance – collateral standard: Usability.*
- *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 Eclipse 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 device modifications made to the Eclipse PRO. The results of these activities demonstrate that the Eclipse PRO is safe and effective when used in accordance with its intended use and labeling.

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