K110001

JUN 14 2011

510(k) Premarket Notification
Spacelabs Healthcare
Spacelabs Pathfinder SL Holter Analyzer
510(k) Summary

Submission Date:	25 May 2010
Submitter:	Spacelabs Healthcare Ltd. 1 Harforde Court, John Tate Road Hertford, SG13 7NW United Kingdom
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Manufacturing Site:	Spacelabs Healthcare 5150 220th Avenue SE Issaquah, WA 98029
Trade Name:	Spacelabs Model 90217A Ambulatory Blood Pressure (ABP) Monitor
Common Name:	Computer, Diagnostic, Programmable
Classification Name:	Holter Analyzer
Classification Regulation:	21 CFR §870.1425
Product Code:	DQK

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Substantially Equivalent Devices:	*New Spacelabs Model*	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
	Spacelabs Pathfinder SL Holter Analyzer	K993620	Spacelabs (Del Mar Medical Systems) Impresario™ Ambulatory ECG (Holter) Arrhythmia Analysis Software
		K951902	Spacelabs (Reynolds Medical Ltd) Pathfinder 700 Holter Analyzer
		K042745	Spacelabs (Del Mar Reynolds Medical, Inc.) Lifescreen Apnea

Device Description:

Spacelabs Pathfinder SL Holter Analyzer (Pathfinder SL) is a software-only ECG analysis system for recording and analyzing up to 24 hours of 12 lead EGC or seven days of continuous 3 lead ambulatory ECG. Pathfinder SL is designed to operate on a Microsoft Windows® based personal computer (PC) platform, and contains provisions for networking. Pathfinder SL is compatible with Windows XP, Vista, or Windows 7 32-bit (ensure the latest service packs installed) operating systems.

Pathfinder SL is used in conjunction with Spacelabs Healthcare's Sentinel Cardiology Information Management System (Sentinel), and is sold only for use with Sentinel.

In conjunction with Sentinel, Pathfinder SL can acquire data from Spacelabs Holter recorders, analyze up to 12 channels of ECG data, providing classification, editing, and reporting of arrhythmia, ST segment, QT segment, heart rate variability and pacer performance, and allows the operator to construct a report for physicians to use within their diagnosis of patients. Pathfinder SL is compatible with Lifecard CF, Lifecard 12, evo and Aria Holter Recorders.

ECG from pre-existing stored analyses created with the previous Spacelabs Healthcare Impresario or Pathfinder Holter analyzer systems can be analyzed from scratch using Pathfinder SL.

Pathfinder SL should be used by an operator trained in electrocardiography. A qualified medical practitioner should make any diagnosis.

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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 Pathfinder SL Holter Analyzer is intended for use on adult patients only as a screening device to determine the need for clinical diagnosis and evaluation by polysomnography based on the patient's score. The ECG recording may be obtained at any location specified by a physician including home, hospital or clinic. Subjects screened for sleep apnea should have periods of sleep ofat least 4 hours duration during which the ECG is predominantly sinus rhythm in nature.

Technology Comparison:

The Pathfinder SL employs the same technological characteristics as the predicate device.

Summary of Performance Testing:

Biocompatibility

The Pathfinder SL is software only and does not directly or indirectly contact the patient. Therefore, biocompatibility testing is not necessary for the Pathfinder SL.

Electrical Safety

The Pathfinder SL is software only. Therefore, electrical safety testing is not necessary for the Pathfinder SL.

Electromagnetic Compatibility (EMC) Testing

The Pathfinder SL is software only. Therefore, EMC testing is not necessary for the Pathfinder SL.

Performance Testing

The Pathfinder SL was tested for performance in accordance with internal requirements and the applicable portions of the following Standards:

- *IEC 60601-2-47: 2001, Medical electrical equipment – Particular requirements for the safety including essential performance, of ambulatory electrocardiographic systems;*
- *ANSI/AAMI EC57: 1998, Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms; and*
- *ANSI/AAMI EC38: 1998, Ambulatory electrocardiographs*

Test results indicated that the Pathfinder SL complies with its predetermined specification and with the applicable Standards.

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Software Testing

Software device modifications made to the Pathfinder SL were designed and developed according to a robust software development process, and were 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; and*
- *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02.*

Test results indicate that the Pathfinder SL complies with its predetermined specification.

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of the software device modifications made to the Pathfinder SL. The results of these activities demonstrate that the Pathfinder SL is safe and effective when used in accordance with its intended use and labeling.

Therefore, the Pathfinder SL is considered substantially equivalent to the predicate devices.

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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

Spacelabs Healthcare Ltd.
c/o Mr. Thomas Kroenke
Speed to Market, Inc.
PO Box 3018
Nederland, CO 80466

JUN 14 2011

Re: K110001
Trade Name: Spacelabs Pathfinder SL Holter Analyzer
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK and MNR
Dated: May 28, 2011
Received: June 1, 2011

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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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): K110001

Device Name: Spacelabs Pathfinder SL Holter Analyzer

Indications for 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.

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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 K110001