K103732 P1/3

510(k) Premarket Notification
Spacelabs Healthcare Ltd.
Spacelabs Model 90217A ABP Monitor
510(k) Summary

FEB - 4 2011

Submission Date:	29 November 2010
Submitter:	Spacelabs Healthcare Ltd. 1 Harforde Court, John Tate Road Hertford, SG13 7NW United Kingdom
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Official Contact:	Thomas Kroenke Principal Consultant Speed To Market, Inc. PO Box 3018 Nederland, CO 80466 USA tkroenke@speedtomarket.net 303 956 4232
Manufacturing Site:	Spacelabs Healthcare Ltd. 1 Harforde Court, John Tate Road Hertford, SG13 7NW United Kingdom
Trade Name:	Spacelabs Model 90217A Ambulatory Blood Pressure (ABP) Monitor
Common Name:	Non-invasive Blood-Pressure Measurement System
Classification Name:	System, Measurement, Blood-pressure, Non-invasive
Classification Regulation:	21 CFR §870.1300
Product Code:	DXN

Substantially Equivalent Devices:

New Spacelabs Model	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
Spacelabs Model 90217A Ambulatory Blood Pressure (ABP) Monitor	K855127	Spacelabs Ambulatory Blood Pressure Monitor Spacelabs #90202

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Device Description:

The Spacelabs Model 90217A Ambulatory Blood Pressure (ABP) Monitor (Model 90217A) is a small, lightweight unit designed to take non-invasive blood pressure (NIBP) and heart rate (HR) measurements for a 24 hour, 48 hour, or longer period. These measurements are recorded in the monitor and may be transferred to Spacelabs ABP analysis systems.

The Model 90217A allows the use of an automated or manual inflation system, and utilizes the oscillometric NIBP measurement method. The pressure sensor signal is amplified, digitized by an analog to digital converter (ADC), and supplied to a microprocessor which has control of the pump and vent valve. Measurements are made during the stepwise deflation of the cuff. The Model 90217A NIBP and HR algorithms are identical to that of the predicate. Additionally, the NIBP patient cuffs used with the Model 90217A are the same as those used with the predicate. A block diagram of the Model 90217A is presented in *Figure 2*.

The Model 90217A is powered by three (3) "AA" alkaline or rechargeable NiCad batteries; there is no capability to connect the Model 90217A to AC mains power. A lithium battery is used to provide backup power for the Model 90217A memory. Both battery types need to be periodically replaced.

The Model 90217A is carried in a pouch that is strapped and/or belted to the side of the patient. NIPB and HR measurements are taken using a blood pressure cuff attached to the patients arm. This information is recorded in the monitor, and can be transferred over a modem link, or by direct connection, between the Model 90217A and one of the ABP analysis systems.

Intended Use:

The Spacelabs Model 90217A Ambulatory Blood Pressure (ABP) Monitor is a small, lightweight unit designed to take blood pressure and heart rate measurements for a 24 hour, 48 hour, or longer period. These measurements are recorded in the monitor and may be transferred to Spacelabs ABP analysis systems.

Technology Comparison:

The Model 90217A employs the same technological characteristics as the predicate devices take non-invasive blood pressure (NIBP) and heart rate (HR) measurements.

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Summary of Performance Testing:

Biocompatibility	The patient contact NIBP cuffs used with the Model 90217A are the same as those used with the predicate, and were cleared with the predicate. Therefore, biocompatibility testing is not necessary for the Model 90217A.
Electrical Safety	The Model 90217A was tested for patient safety in accordance with applicable Standards. Test results indicated that the Model 90217A complies with its predetermined specification and with the applicable Standards.
Electromagnetic Compatibility Testing	The Model 90217A was tested for EMC in accordance with applicable Standards. Test results indicated that the Model 90217A complies with its predetermined specification and with the applicable Standards.
Performance Testing	The Model 90217A was tested for performance in accordance with applicable Standards. Test results indicated that the Model 90217A complies with its predetermined specification and with the applicable Standards.
Software Testing	Software for the Model 90217A was designed and developed according to a robust software development process, and was rigorously verified and validated. Test results indicated that the Model 90217A complies with its predetermined specification.
Conclusion	Based upon a comparison of devices and performance testing results, Model 90217A is substantially equivalent to the predicate device.

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
Application Correspondent
Speed To Market, Inc.
PO Box 3018
Nederland, CO 80466

FEB – 4 2011

Re: K103732
Trade/Device Name: Model 90217A Ambulatory Blood Pressure (ABP) Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood-Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: November 30, 2010
Received: December 22, 2010

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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): K 103732

Device Name: Spacelabs Model 90217A Ambulatory Blood Pressure (ABP) Monitor

Indications for Use: The Spacelabs Model 90217A Ambulatory Blood Pressure (ABP) Monitor is a small, lightweight unit designed to take blood pressure and heart rate measurements for a 24 hour, 48 hour, or longer period. These measurements are recorded in the monitor and may be transferred to Spacelabs ABP analysis systems.

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

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