K082045
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July 11, 2008

510(K) Summary of Safety and Effectiveness

The 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 1992.

Subject:	510(k) Summary of Safety and Effectiveness Information for the Spacelabs Medical mCare 300 Vital Signs Monitor, Model 91220.
Submitter:	Spacelabs Medical, Inc. 5150 220th Avenue SE Issaquah, WA 98029 David J. Geraghty Phone: 425-657-7200 Fax: 425-657-7210 Email: david.geraghty@slmd.com
Proprietary Name:	Spacelabs Medical mCare 300 Vital Signs Monitor, Model 91220
Common Name and Classification:	Monitor, Physiological, Patient (with Arrhythmia Detection or Alarms) (74 MHX, §870.1025, Class II)
Device Description:	The Spacelabs Medical mCare 300 Vital Signs Monitor Model 91220 (mCare 300), is a portable patient monitoring device intended to be used by clinicians and medically qualified personnel for monitoring physiological parameters; ECG, respiration, noninvasive and invasive blood pressure, body temperature, SpO_2, or End tidal CO_2 or $ETCO_2$; in neonatal, of pediatric and adult patients. This device is designed to be used in all general hospital and alternate care environments. This device is available for sale only upon the order of a physician or licensed health care professional.

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Intended Use:	The Spacelabs Medical mCare 300, Model 91220, Vital Signs Monitor is indicated for use in adult, pediatric and neonate patient populations wherever there is a need for the monitoring of ECG, respiration, invasive or noninvasive blood pressures, body temperature, functional arterial oxygen saturation, or expired or minimum inspire CO_2. The Spacelabs Medical mCare 300, Model 91220, Vital Signs Monitor is a prescription device intended to be used by healthcare professionals in all areas of a healthcare facility.
Test Discussion:	The revised mCare 300 is substantially equivalent in design concepts, technologies and materials to the mCare 300 that was originally cleared under 510(k) number K062095 and the Press-Mate BX-10 Vital Signs Monitor (BX-10) by Colin (now Omron) that was cleared under 510(k) number K032857. The mCare 300 originally incorporated a Welch Allyn NIBP module, the revised mCare 300 and the basis for this submission, uses the Omron (formally Colin) M3200 NIBP module. The M3200 NIBP module was an integral part of the BX-10 cleared under 510(k) number K032857. With the exception of the NIBP feature, this change has no significant impact on the other features or functions (respiration, ECG, invasive blood pressure, body temperature, Sp02, or End Tidal CO_2 or $ETCO_2$) of the originally cleared mCare 300. The change in NIBP modules was made for supply reasons. The NIBP module revision to the mCare 300 was validated through rigorous testing that, in part, supports the compliance of the mCare 300 to the various standards identified in this submission. Additionally, the software revision, to accommodate the new NIBP module was developed following a robust software development process and was fully specified and validated.
Test Conclusion:	The mCare 300 with the new NIBP module is substantially equivalent to its predicate devices in design concepts, technologies and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Spacelabs Medical, Inc.
c/o Mr. David J. Geraghty
Manager, Regulatory & Quality
5150 220th Avenue, SE
P.O. Box 7018
Issaquah, WA 98029

AUG - 1 2008

Re: K082045
Trade/Device Name: Spacelabs Medical, mCare 300, Vital Signs Monitor, Model 91220
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
(including ST-segment measurement and alarm)
Regulatory Class: Class II
Product Code: MHX
Dated: June 22, 2008
Received: June 24, 2008

Dear Mr. David J. Geraghty:

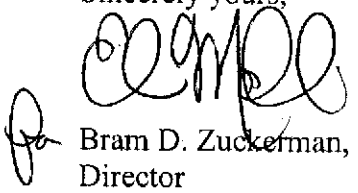
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082045

Indications for Use

510(k) Number (if known): K_____

Device Name: Spacelabs Medical, mCare 300, Model 91220, Vital Signs Monitor

Indications For Use: The Spacelabs Medical, mCare 300, Model 91220, Vital Signs Monitor is indicated for use in adult, pediatric and neonate patient populations wherever there is a need for the monitoring of ECG, respiration, invasive or noninvasive blood pressures, body temperature, functional arterial oxygen saturation, or expired or minimum inspire CO_2.

The Spacelabs Medical, mCare 300, Model 91220, Vital Signs Monitor is a prescription device intended to be used by healthcare professionals in all areas of a healthcare facility.

Prescription Use XX (Part21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** _____ (21 CFR 801 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 K082045