K062095

510(k) Premarket Notification
Spacelabs Medical
mCARE 300 Vital Signs Monitor, Model 91220
Summary of Safety and Effectiveness

SEP 29 2006

July 17, 2006

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. PO Box 7018 Issaquah, WA 98029 David J. Geraghty Phone: 1 425 657 7200 Fax: 1 425 657 7207 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, 21CFR 870.1025, Class II) Special Controls - The guidance document entitled "Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm" will serve as the special control.
Device Description:	The Spacelabs Medical mCARE 300 Vital Signs Monitor, Model 91220, 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, Sp02, or End tidal C02 or ETC02; 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.
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 mCARE 300, Model 91220, Vital Signs Monitor and is substantially equivalent in design concepts, technologies and materials the Spacelabs Medical COSMOS SYSTEM, model 95000, patient monitor (K013046) with respect to ECG, respiration, IBP and arrhythmia processing; to the Welch-Allyn MS53000 (K031740) with respect to NIBP, the to Nellcor N-595 (K012740) with respect to SpO2 and to the Respironics Capnostat 5 (042601) and Lo Flo C5 (K053174) with respect to EtCO2.

The mCARE 3000 Vital Signs Monitor successfully underwent testing to demonstrate conformance to the Special Controls established for 21CFR 807.1025, "Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm".

The mCARE 300 Vital Signs Monitor was validated through rigorous testing that, in part, support the compliance of the mCARE 300 Vital Signs Monitor to the Standards mentioned in Section 9.0 of this submission. Additionally, the software for the mCARE 300 Vital Signs Monitor was developed following a robust software development process and was fully specified and validated.

Test Conclusion:

The mCARE 300, Model 91220, Vital Signs Monitor 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

SEP 29 2006

Spacelabs Medical Inc.
c/o Mr. David J. Geraghty
Manager, Regulatory and Quality
5150 220th Ave. SE
PO Box 7018
Issaquah, WA 98027

Re: K062095
Trade Name: mCARE 300 Vital Signs Monitor, Model 91220
Regulation Number: 21 CFR 870.1025
Regulation Name: Physiological Patient Monitor (with Arrhythmia Detection or Alarms)
Regulatory Class: Class II (two)
Product Code: MHX
Dated: July 19, 2006
Received: July 24, 2006

Dear Mr. 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 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,

B Zuckerman 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): K062095

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 (Part 21 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 OF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062095