

K972502

MAY 28 1998



15220 N.E. 40th Street  
P.O. Box 97013  
Redmond, Washington 98073-9713  
425-882-3100

510(k) SAFETY AND EFFECTIVENESS SUMMARY

Spacelabs Medical Integrated Multiparameter Module 90496

- 1. Submitter's Name      Russ Garrison  
Director of Regulatory Affairs
- Company                    Spacelabs Medical Inc.  
15220 N.E. 40th Street  
Redmond, WA 98073
- Telephone:                (425) 882-3913
- Facsimile:                 (425) 867-3550
  
- 2. Name of Device        Spacelabs Medical Integrated Multiparameter Module 90496
  
- Classification:           Arrhythmia Detector and Alarm  
74DSI; 21 CFR 870.1025  
Class III
  
- Noninvasive Blood Pressure Measurement System  
74DXN; 21 CFR 870.1130  
Class II
  
- Oximeter  
74DQA; 21 CFR 870.2700  
Class II
  
- Blood Pressure Computer  
74DSK; 21 CFR 870.1110  
Class II
  
- Clinical Electronic Thermometer  
80BWX; 21 CFR 880.2910  
Class II
  
- Monitor, Cardiac Output, Thermal  
74KFN; 21 CFR 870.1435  
Class II

3. Predicate Device(s) We consider the Spacelabs Medical Integrated Multiparameter Module 90496 to be substantially equivalent to a combination of features offered by predicate devices, with identical intended uses for each of the seven (7) physiological parameters that may be monitored by the Model 90496.
- Spacelabs Medical believes that the Integrated Multiparameter Module 90496 is substantially equivalent to a combination of the Spacelabs Medical Integrated Multiparameter Module 90470 (510[k] reference K952912) for monitoring of electrocardiographic signals, respiration, noninvasive pressure measurement and pulse oximetry oxygen saturation (SpO<sub>2</sub>); Spacelabs Medical Integrated Multiparameter Expansion Housing Module 90352 (510[k] K945429) for monitoring of temperature and invasive blood pressure measurement, electrocardiographic activity and respiration; Spacelabs Medical 12-Lead ECG and ST Segment Module 90492 (510[k]s K942058 and K962970) for 12-lead electrocardiogram monitoring; and the Baxter Edwards Critical Care Division Explorer Cardiac Output Computer (510[k] K896930) for monitoring cardiac output.
4. Device Description The Integrated Multiparameter Module 90496 is a slim, lightweight singular modular unit that, when used in conjunction with a Spacelabs Medical Patient Care Management System (PCMS), provides the capability to acquire various common physiologic data in a clinical setting.
- The Module is the primary interface to the patient being monitored. The Module is capable of acquiring and processing ECG, respiration, invasive and noninvasive blood pressure, temperature, cardiac output, and SpO<sub>2</sub> parameters for a single patient. The Module accumulates the patient physiological data of interest and provides both waveform and digital data to a Spacelabs Medical monitor via SDLC communications. The monitor will provide the display capabilities for the care provider.
5. Intended Use The Spacelabs Medical Integrated Multiparameter Module 90496 is intended for use with the PCMS to acquire, monitor, and process various clinical parameters from adult or neonatal/infant populations in any type of clinical environment other than home use. Physiologic parameters that may be monitored include cardiac activity, respiration, invasive and noninvasive blood pressure, temperature, oxygen saturation (SpO<sub>2</sub>), and cardiac output. Acquired data may then be communicated to an information network for display, recording, editing and analysis.
6. Comparison of Technological Characteristics We consider the Integrated Multiparameter Module 90496 to be substantially equivalent to a combination of systems currently marketed by Spacelabs Medical and, for the cardiac output feature, to the Edwards Critical Care Division of Baxter Healthcare Corporation.

The design, components, storage technology and energy source are similar to its predicate devices. All systems provide a means for interfacing with a patient, collecting parameter specific physiologic data, and processing the data for alarm generation and display of numeric values and waveforms on a bedside or central monitoring system.

The only significant differences between the Spacelabs Medical Integrated Multiparameter Module 90496 and the comparable systems are in the physiologic feature sets offered by each the systems and in the hardware packaging of the feature sets of the Integrated Multiparameter Module 90496 into one modular unit designed to be compatible with the existing Patient Care Monitoring System (PCMS) currently offered by Spacelabs Medical.

#### 7. Testing

The Spacelabs Medical Integrated Multiparameter Module 90496 has been subject to extensive safety and performance testing. Final testing for the system included various performance tests designed to ensure that the device meets all functional requirements and performance specifications. Safety testing has been performed by third party agencies to ensure the device complies to applicable industry and safety standards. The Integrated Multiparameter Module 90496 has also been tested to assure compliance to the requirements of various standards, including IEC 601.1, ANSI/AAMI EC11 and EC13, AAMI ECAR-1987, and ANSI/AAMI SP-10 for accuracy testing.

In conclusion, the Spacelabs Medical Integrated Multiparameter Module 90496 is as safe and effective as the predicate devices and raises no new issues.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 28 1998

Mr. Russ Garrison  
SpaceLabs Medical, Inc.  
15220 N.E. 40<sup>th</sup> Street  
P.O. Box 97013  
Redmond, WA 98073-9713

Re: K972502  
SpaceLabs Medical Integrated Multiparameter Module 90496  
Regulatory Class: III (three)  
Product Code: 74 DSI  
Dated: February 25, 1998  
Received: February 27, 1998

Dear Mr. Garrison:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Russ Garrison

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE

Page 1 of 2

510(k) Number (if known): Not Known (New Submission) **K972502**

Device Name: Spacelabs Medical Integrated Multiparameter Module 90496

### Indications for Use:

*Condition to be screened, monitored, treated or diagnosed.*

Patient conditions indicated by abnormalities in various physiologic parameters, including ECG waveform, respiratory effort, invasive and noninvasive blood pressure measurements, temperature, cardiac output, and pulse oximeter (SpO<sub>2</sub>) readings.

*Prescription use only.*

Yes. Caution statement is provided in the introductory page of the Patient Care Management System which includes the operating instructions for this Module.

*Parts of body applied to.*

Specific to the physiologic parameter being monitored, accessories may be applied externally to the chest and limbs or invasively into the blood stream.

*Frequency of use.*

Frequency as directed by physician.

*Physiological purpose.*

In conjunction with clinical findings, a screening and diagnostic tool for use in:

- assessing electrical activity of the heart in order to detect abnormal cardiac rhythms, including life threatening events such as high and low heart rates, asystole and ventricular fibrillation, as well as, in adults, the detection of rhythms such as ventricular runs, tachycardia, and ST segment deviations;
- monitoring respiratory effort to detect abnormal respiration events such as high and low respiration rates and episodes of apnea;

- continuous monitoring of invasive pressure signals to detect abnormal events such as high and low pressure;
- episodic monitoring of noninvasive pressure signals to detect abnormal events such as high and low pressure;
- continuous monitoring of temperature signals to detect abnormal events such as high and low body temperature;
- monitoring of the patient's pumping ability of the heart and various hemodynamic values to detect abnormal flow volumes; and
- noninvasive, continuous monitoring of pulse oxygen saturation signals in order to detect desaturation due to abnormal pulmonary/circulatory functions.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

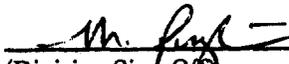
\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number \_\_\_\_\_