K 983996

JUN 3 1999

510(k) SAFETY AND EFFECTIVENESS SUMMARY

Spacelabs Medical Ultraview™ Digital Telemetry System

1.	Submitter's Name	Nancy J. Gertlar Manager, Regulatory
	Company	Spacelabs Medical, Inc. 15220 N.E. 40th Street Redmond, WA 98073
	Telephone	(425) 867-7315
	Facsimile	(206) 867-3550
2.	Name of Device	Spacelabs Medical Ultraview™ Digital Telemetry System
	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
3.	Predicate Device(s)	The Ultraview Digital Telemetry System is substantially equivalent to a combination of features offered by predicate devices, with identical intended uses, for the three (3) physiological parameters that may be telemetrically monitored within a hospital environment by the System.. Specifically, the Ultraview Digital Telemetry System is substantially equivalent to a combination of the: Spacelabs Medical Ultraview™ Integrated Multi-parameter Module 90496 (510[k] reference K972502) in that both modules offer the capability for the monitoring of electrocardiographic signals,

noninvasive pressure measurement and pulse oximetric oxygen saturation (SpO2);

Spacelabs Medical Ultralite™ Ambulatory Blood Pressure Monitor 90217 (510[k] reference K855127) for the monitoring of noninvasive blood pressure measurements via remote programming and digital data retrieval capabilities;

Spacelabs Medical Single Lead Digital Telemetry Transmitter Model 90339 (510[k] reference 952885), Dual Lead Digital Telemetry Transmitter Model 90341 (510[k] reference 925510) and the Quad Lead Digital Telemetry Transmitter Model 90340 (510[k] reference 781836) for the monitoring of electrocardiographic signals via remote programming and digital data retrieval capabilities; and

Hewlett Packard Company's M2601A Viridia Transmitter and M2603A Viridia Receiver, marketed under the system model number of M2600A (510[k] reference 961165) for the integration of ECG, with support for arrhythmia monitoring and ST segment analysis, and continuous and episodic SpO2 operations in a telemetric monitoring system.

4. Device Description

The Ultraview Digital Telemetry System is a multiple parameter system which provides the capability for wireless central station monitoring of patients within hospitals or medical center facilities. This telecommunications feature converts bedside monitors to telemetry operation and works with a portable monitor for the transport of telemetrically-monitored patients to allow for the remote programming and data retrieval of clinical parameters specific to patient populations, clinical protocols, or operating preferences. Physiological parameters supported by the System are the acquisition and monitoring of electrocardiographic signals (ECG), pulse oximetric oxygen saturation (SpO2) and noninvasive blood pressure (NIBP) parameters, based upon the System configuration options selected by the clinician.

The devices subject to this submission are the Models 90343, 90347, and 90478. Each Ultraview Digital Telemetry System configuration consists of a battery-operated Telemetry Transmitter, a Receiver Module, and an antenna system. The Ultraview Digital Telemetry Multi-Parameter Transmitter Model 90343 is a wideband VHF unit that provides 5-electrode ECG and continuous or episodic SpO2 monitoring capabilities, with an optional noninvasive blood pressure (NIBP) interface when connected to a Spacelabs Medical Model 90217Ambulatory Blood Pressure (ABP) Monitor (K855127). The Ultraview Digital Telemetry ECG Transmitter Model 90347 is identical to the Model 90343 with the SpO2 measurement function and ABP communications capabilities removed.

The Ultraview Digital Telemetry System interfaces to a patient using standard accessories including ECG electrodes and lead wires, NIBP hoses and cuffs, SpO2 cables and sensors, and adapter cables to connect these accessories to the Transmitter. The telemetry system sends raw ECG vectors or pre-processed SpO2 and NIBP data, based upon the capability of the selected Transmitter, to the VHF version of the Model 90478 Modular Receiver via a diversity antenna system.

The Modular Receiver collects and processes parameter specific physiologic data for alarm generation and display of numeric values and waveforms on a Spacelabs Medical Patient Care Management System (PCMS) Monitor or Ultraview Care Network via SDLC communications. The monitor provides the display, review, editing and analysis capabilities for the care provider. Hard copy records may be provided by the wide variety of Spacelabs Medical printers and recorders that can be interfaced by either Ethernet or SDLC communications.

5. Intended Use

The Spacelabs Medical Ultraview Digital Telemetry System, when used in conjunction with a Spacelabs Medical PCMS Patient Monitor or Ultraview Care Network, provides a means for the continuous

monitoring of electrocardiographic signals in order to detect abnormal cardiac rhythms, including life-threatening events such as high and low heart rates, asystole, and ventricular fibrillation. Optionally, on adult patients, additional abnormal cardiac rhythms, such as ventricular runs, tachycardia, and ST segment deviations are detected.

The Ultraview Digital Telemetry System also provides a means for the episodic monitoring of noninvasive blood pressure (NIBP) signals to detect abnormal events such as high and low blood pressure. The System also provides a means for both continuous and episodic monitoring of pulse blood oxygen saturation signals in order to detect desaturation caused by abnormal pulmonary/circulatory functions.

The Spacelabs Medical Ultraview Digital Telemetry System Models 90343 and 90347 are intended for use with either adult or neonatal patient populations in a hospital environment. When the NIBP option is selected in the Model 90343 configuration, the NIBP feature is to be used with adult patient populations only.

6. Comparison of Technological Characteristics

We consider the Ultraview Digital Telemetry System to be substantially equivalent to a combination of systems currently marketed by Spacelabs Medical and, for the integration of physiological parameters into a telemetry system, to the Hewlett Packard System Model Number M2600A. The design, components, storage technology and energy source are similar to its predicate devices. The comparable systems all 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 Ultraview Digital Telemetry System and the comparable systems are in the physiologic feature sets offered by each of the systems and in the hardware packaging of the multi-

		parameter feature sets of the Ultraview Digital Telemetry Transmitters into one modular unit designed to be compatible with the existing Patient Care Monitoring System (PCMS) and Ultraview Care Network currently offered by Spacelabs Medical.
7.	Testing	The Spacelabs Medical Ultraview Digital Telemetry System will be subject to extensive safety and performance testing prior to release. Final testing for the system includes various performance tests designed to ensure that the device meets all of its functional requirements and performance specifications. Safety testing has been or will be performed by third party agencies to ensure the device complies to applicable industry and safety standards. The Ultraview Digital Telemetry System will also be tested to assure compliance to the requirements of various standards, including ANSI/AAMI EC13 and AAMI ECAR-1987.

In conclusion, the Spacelabs Medical Ultraview Digital Telemetry System is as safe and effective as its predicate devices and raises no new issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 1999

Ms. Nancy J. Gertlar
Spacelabs Medical
15220 N.E., 40th Street
P.O. Box 97013
Redmond, WA 98073-9713

Re: K983996
Ultraview Digital Telemetry System
Regulatory Class: III (three)
Product Code: MHX
Dated: March 4, 1999
Received: March 5, 1999

Dear Ms. Gertlar:

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 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). 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 (Premarket 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 premarket 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.

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, ²Misbranding by reference to premarket notification² (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

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

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

Device Name: Spacelabs Medical Ultraview™ Digital Telemetry System

Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

OR

Over-The-Counter Use

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

510(k) Number K983996