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K992749

510(K) SAFETY AND EFFECTIVENESS SUMMARY

Spacelabs Medical Ultraview™ Waveform Pager System

1.	Submitter's Name	Irene Jaworski Director, Regulatory Affairs and Quality
	Company	Spacelabs Medical, Inc. 15220 NE 40th Street Redmond, WA 98073
	Telephone	(425) 882-3913
	Facsimile	(425) 867-3550
2.	Name of the Device	Spacelabs Medical Ultraview™ Waveform Pager System
	Classification	System, Network and Communication, Physiological Monitors 74MSX, 870.2910 Class III
3.	Predicate Device(s)	The Spacelabs Medical Waveform Pager System is substantially equivalent to the K973527 Data Critical Corporation's Cardio-Pager System and the K971868 Marquette Medical Systems Impact Pager System. (Note: Data Critical Corporation's Cardio-Pager System is the same device as the Marquette Medical System's Impact Pager System.) The Spacelabs Medical Waveform Pager System and its predicate devices serve as secondary alarm notification systems that forward patient data (text and waveforms) from the patient monitoring devices to a graphics pager(s). The Waveform Pager System and its predicate devices passively gather alarm event information (including waveforms) from the patient monitoring devices to a graphics pager(s). The Waveform Pager System and its predicate devices passively gather alarm event information (including waveforms) from the patient monitoring network and use standard paging technology to deliver this information to mobile caregivers.
4.	Device Description	The Spacelabs Medical Ultraview™ Waveform Pager System provides caregivers within a clinical environment the ability to remain mobile and be notified when an alarm event occurs. Typically, alarm notification by the pager occurs within 4-8 seconds of an alarm event on the patient

monitor. The pager provides an audio or vibrating alert along with a series of displays showing patient identification, alarm parameters, and up to a 12-second waveform snapshot.

The administration module allows convenient assignment of patients to caregivers from any location on the network, including WinDNA-enabled Universal Clinical Workstations. Patient status updates can also be scheduled for dispatch to the pager on a repeating basis if desired.

This system is not a replacement for the primary alarm notification system. The delivery of pages cannot be guaranteed or verified. The Waveform Paging System is intended to augment alarm notification. It is not intended or designed to replace monitoring personnel, good clinical judgment, or to be used in place of bedside and remote alarm notification, or the Alarm Watch function of the monitor.

The device subject to this submission is Model 91841. Each Spacelabs Medical Ultraview™ Waveform Pager System consists of a Server which collects and formats data from the monitoring network, a Transmitter which broadcasts the information to the mobile caregiver, and a Receiver which receives the broadcast and displays the formatted information.

5. Intended Use

The intended use of the Spacelabs Medical Ultraview™ Waveform Pager System is to interface with the Spacelabs monitoring network in order to provide a secondary means of annunciating and displaying patient alarm information to mobile healthcare providers. The device is indicated for use in real-time monitoring of routine patient status and alarm events. The pager is intended to serve as a parallel, redundant mechanism to inform the clinical staff of patient events. The Ultraview™ Waveform Pager System is intended for use as a secondary alarm in any hospital environment currently using or intending to use a Spacelabs patient-monitoring network. The Waveform Paging System supplements the primary patient-monitoring system by providing a forwarding mechanism for annunciating and displaying patient alarm events and the critical information associated with the events - including parameter values and waveforms, typically within 4 - 8

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		seconds of an alarm event on the patient monitor. The pager provides an audio or vibrating alert along with a series of displays showing patient identification, alarm parameters, and up to a 12-second waveform snapshot. The Spacelabs Medical Ultraview™ Waveform Pager System is a secondary alarm. It does not replace the primary alarm function on the monitor.
6.	Comparison of Technological Characteristics	The underlying technological characteristics of the Spacelabs Medical Ultraview™ Waveform Pager System are similar to and functionally equivalent to those of the predicate devices. The systems collect substantially the same information. The collected data is transmitted to the mobile caregiver(s) using standard technologies. The Receivers are lightweight graphical pagers. The transmitted information is displayed on the pagers as a sequence of message displays that can be saved for later reference. The systems can be configured to forward patient vital sign updates to caregivers at defined intervals. The differences between the Spacelabs Medical Ultraview™ Waveform Pager System and its predicate devices are minor and do not raise new issues of safety and/or effectiveness in comparison with the predicate devices. The Spacelabs Medical Ultraview™ Waveform Pager System has a higher resolution display than the predicate devices. The Spacelabs Medical Ultraview™ Waveform Pager System provides a longer snapshot of waveform data for the alarming parameter than the predicate devices.
7.	Testing	The Spacelabs Medical Ultraview™ Waveform Pager 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.

In conclusion, the Spacelabs Medical Ultraview™ Waveform Pager 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

JAN 14 2000

Irene Jaworski
Director Regulatory Affairs and Quality
Spacelabs Medical
15220 N.E. 40th Street
P.O. Box 97013
Redmond, Washington 98073-9713

Re: K992749
Trade Name: Ultraview Waveform Pager System
Regulatory Class: III (three)
Product Code: MSX
Dated: November 29, 1999
Received: November 30, 1999

Dear Ms. Jaworski:

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, "Misbranding by reference to premarket notification" (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,

for

Celia M. Witten, Ph.D., M.D.
Acting 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): K992749

Device Name: Spacelabs Medical Ultraview™ Waveform Pager System

Indications for Use:

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The Spacelabs Medical Ultraview™ Waveform Pager System is a secondary alarm. It does not replace the primary alarm function on the monitor.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for C. W. Hen

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K992749

Prescription Use ✓
(Per 21 CFR 801.109)
(Optional format 1-2-96)

OR Over-The-Counter Use ___