K962811

SpaceLabs Medical

15220 N.E. 40th Street
P.O. Box 97013
Redmond, Washington 98073-9713
206-882-3700

JUN 24 1997

510(k) SUMMARY

SpaceLabs Medical Multi-Disclosure Workstation

1.	Submitter's Name	SpaceLabs Medical Inc. 15220 N.E. 40th Street Redmond, WA 98073
	Telephone:	(206) 882-3913
	Facsimile:	(206) 867-3550
2.	Name of Device	**SpaceLabs Medical Multi-Disclosure Workstation**
	Classification:	Display, Cathode-Ray Tube; 74DXJ; 21 CFR 870.2450
3.	Predicate Device(s)	The SpaceLabs Medical Multi-Disclosure Workstation is an accessory to the SpaceLabs Medical PCMS network to offer support for the collection, review, editing, archiving and printing of patient waveform data available from the network. This device is substantially equivalent to workstations currently marketed by Hewlett-Packard Company and Marquette Electronics, Inc. Hewlett-Packard markets the M1251A Full Disclosure Review System (K905788) which collects waveform data and provides support for the review, editing, archival and printing of this data. The Marquette Muse Cardiology Management System (K840932) includes these features for the on-line review of 12-lead ECG reports and their subsequent archival for later retrieval.
4.	Device Description	The SpaceLabs Medical Multi-Disclosure Workstation is a personal computer accessory with an Ethernet link to the SpaceLabs Medical PCMS network. The Workstation is a software application for a generally-available Pentium® based computer system with an SVGA monitor, laser printer and keyboard, with optional mouse and CD-ROM drive, running Windows NT. The SpaceLabs Medical proprietary software consists of modules for monitoring census information on the PCMS network, collecting waveform, 12-lead and alarm data from the network, processing waveform data for display, printing reports, and managing patient information. The system provides full-disclosure waveform data, which provides a means to review continuous waveform data from a patient for one or more channels of data. Strips or disclosure print-outs of the data may be reviewed on-screen, printed, or saved for archival purposes and later side-by-side comparisons

		of previously stored data. The user may select from a variety of viewing and printing formats.
5.	Intended Use	The SpaceLabs Multi-Disclosure Workstation is intended for use with the SpaceLabs PCMS monitoring network to provide for the collection, review, editing, printing and archiving of waveform data records (full disclosure and strips), 12-lead ECG diagnostic reports, and alarm recordings collected by monitors on the network.
6.	Comparison of Technological Characteristics	We consider the device to be substantially equivalent to workstations currently marketed by Hewlett-Packard Company and Marquette Electronics, Inc. The design, components used in the workstation system, and energy source are similar to its predicate devices. All systems provide an interface to a network system in order to provide basic collection, display, review, editing, printing, and archival capabilities for the management of patient data. The only significant difference between the Multi-Disclosure Workstation and these comparable systems is in the number of additional features provided by the Hewlett-Packard and the Marquette workstations when compared to the SpaceLabs Medical Workstation. Specifically, the SpaceLabs Medical Workstation does not support non-network applications and provides no analysis of physiological data.
7.	Testing	The SpaceLabs Medical Multi-Disclosure Workstation has been 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 tests have further been performed by the various manufacturers of the required hardware components to ensure the system complies to applicable industry and safety standards.

In conclusion, the SpaceLabs Medical Multi-Disclosure Workstation is as safe and effective as the 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 24 1997

Mr. Russ Garrison
SpaceLabs Medical, Inc.
15220 N.E. 40th Street
P.O. Box 97013
Redmond, Washington 98073-9713

Re: K962811
SpaceLabs Medical Multi-Disclosure Workstation
Regulatory Class: II (two)
Product Code: 74 DXJ
Dated: March 24, 1997
Received: March 26, 1997

Dear Mr. Garrison:

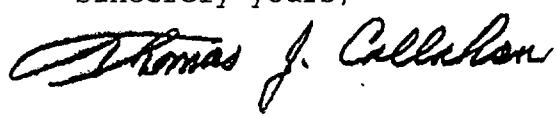
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (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" (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

PREMARKET NOTIFICATION

SpaceLabs Medical Multi-Disclosure Workstation

INDICATIONS FOR USE

510(k) Number: Pending

Device Name: SpaceLabs Medical Multi-Disclosure Workstation

Indications for Use:

1. **Data Access** - Provides the user with the means to collect multiple patient data directly from a hardwired or telemetry Patient Care Management System (PCMS) monitoring network.

2. **Data Storage** - Allows the user to retain up to 48 patient waveforms for up to 48 hours.

3. **Data Display** - Allows the user to pull data from storage or during continuous monitoring by patient and parameter.

4. **Data Editing** - Provides the user with the means to edit 12-lead ECG waveform data and interpretation text from SpaceLabs Medical 12-lead modules connected to the Patient Care Management System (PCMS) monitoring network.

5. **Data Printing** - Allows the user to print time annotated waveforms and patient data on paper for review or archive history.

M. Pugh

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K962811

✓ Prescription Use