MAR 2 5 1997

K962970

SpaceLabs Medical

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

510(k) Summary

SpaceLabs Medical 12-Lead Diagnostic ECG Analysis Option

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 12-Lead Diagnostic ECG Analysis Option**
	Classification:	Arrhythmia Detector and Alarm; 21 CFR 870.1025
3.	Predicate Device(s)	The SpaceLabs Medical 12 Lead Diagnostic ECG Analysis Option is a modification to the existing SpaceLabs Medical 12 Lead ECG Module, as described in K942058. As a result of a business relationship between Mortara Instruments and SpaceLabs Medical, the diagnostic ECG algorithm used in the Diagnostic ECG Analysis Option are identical to those found in the Mortara Instrument ELI300, as described in K933143.

4. The SpaceLabs Medical 12-Lead Diagnostic ECG Analysis Option is a software-only option added to the 90492 module software, and is designed to acquire, analyze and display up to twelve ECG vectors in a standard diagnostic ECG analysis format and to work exclusively within the SpaceLabs Medical 90492 12-lead ECG module. The diagnostic analysis algorithm is that used in the Mortara Instruments ELI 100 (K920627), ELI 200 (K920626A) and ELI 300 (K933143) and is provided by Mortara Instruments as object code. There is no additional hardware required for this option.

   The SpaceLabs Medical Model 90492 ECG module is designed to acquire, process and display up to twelve ECG leads and one respiratory effort signal using standard ECG electrodes. The twelve ECG leads consist of the standard

twelve ECG leads, I, II, III, aVR, aVL, aVF, V1 - V6. The 90492 ECG module is used to monitor patients in the operating room, recovery rooms, intensive care units, in the emergency room, in research settings, or other units where additional ECG leads are desired.

ECG data is displayed as an analog moving waveform or as various static waveforms. The analog ECG is passed through digital filters to eliminate unwanted signals. Standard ECG electrodes are used to interface the patient to the 90492 ECG module. Clinicians will position the electrodes in the customary locations. The electrodes are connected to shielded leadwires which are connected to a shielded cable. The cable is connected to the front of the 90492 module.

5. The SpaceLabs Medical 12-Lead Diagnostic ECG Analysis Option provides a means for performing diagnostic ECG analysis in conjunction with the monitoring functions of the SpaceLabs Medical Model 90492 ECG module. Diagnostic ECG analyzes detailed ECG waveforms in each cardiac cycle and the beat-to-beat variability in order to determine the cardiac rhythm. When used in conjunction with a SpaceLabs Medical Patient Care Management System (PCMS) monitor the SpaceLabs Medical Model 90492 ECG module provides a means for the continuous monitoring of electrocardiographic signals in order to detect abnormal cardiac rhythms, including life-threatening events.

6. The SpaceLabs Medical Model 90492 ECG module with the 12 Lead Diagnostic ECG Analysis Option provides multiple lead monitoring and ECG analysis from electrodes placed on the body surface. Electrical activity of the heart is measured via multiple electrodes placed at various locations on the patient's body. The design, material used, and energy source are similar to its predicate devices.

7. The SpaceLabs Medical 12-Lead Diagnostic ECG Analysis Option has been subjected to extensive safety and performance testing. Final testing for the system includes various bench and performance tests designed to ensure that the device meets all of its functional requirements and performance specifications. Safety tests have been performed to ensure the device complies to all applicable industry and safety standards.

In conclusion, the SpaceLabs Medical 12-Lead Diagnostic ECG Analysis Option is as safe and effective as the predicate device and raises no new issues.

09