

K 962930

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**510(k) SUMMARY**

**SpaceLabs Medical ECG Analysis System**

1. **Submitter's Name** SpaceLabs Medical Inc.  
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2. **Name of Device** **SpaceLabs Medical ECG Analysis System**  
  
**Classification:** Class II Device  
  
Primary Classification:  
Programmable Diagnostic Computer:  
74DQK, 21 CFR 870.1425  
  
Secondary Classification:  
Ambulatory Electrocardiograph with Analysis Algorithm:  
74MLO, 21 CFR 870.2800
  
3. **Predicate Device(s)** We consider the SpaceLabs Medical ECG Analysis System to be substantially equivalent to a combination of features offered by predicate devices, with identical intended uses.  
  
Specifically, SpaceLabs Medical believes that the ECG Recorder component of the system is substantially equivalent to the predicate SpaceLabs Medical ECG Recorder Model 90205 (K844940), which utilizes an analog cassette tape storage system and the Zymed Model 3100 DigiTrak ECG/Pacer Recorder (K942781), which incorporates a solid state flash memory card for data storage.  
  
The Cardiology Workstation component of the SpaceLabs Medical ECG Analysis System is substantially equivalent to the Model 1610 Workstation (K895208) currently marketed by Zymed Corporation in that both products provide for the loading and analysis of up to 3-channel ECG data and for the review, analysis, editing, printing and archiving of ECG waveform data.

**4. Device Description**

The SpaceLabs Medical ECG Analysis System provides the means via a lightweight, portable recording device to continuously record ambulatory patient electrocardiographic (ECG) data over a 24-hour period through a digital solid-state flash memory card for subsequent review and processing on an analysis workstation.

The Workstation consists of a generally-available Pentium® based personal computer system with an SVGA monitor, laser printer and keyboard, with optional mouse and CD-ROM drive, running Windows NT or Windows 95 and SpaceLabs Medical proprietary software. The Workstation is designed to accept input from a digital flash memory card, an analog cassette tape, or via an IR Serial Link to a portable recorder. The workstation also has the capability to interface via an Ethernet link with the SpaceLabs Medical Patient Care Management System (PCMS) to offer support for the collection, review, editing, archiving and printing of patient cardiac waveform data available from a clinical network.

Workstation software provides the capability for the processing of waveform data for display, editing, and analysis, the printing of reports, and the management of patient information. 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 Medical Cardiology Workstation is intended for use with the SpaceLabs Medical ECG Recorder to provide for the analysis of ambulatory ECG data. After the recording is made on the ECG Recorder, the Cardiology Workstation analyzes the ECG waveform data for the duration of the recording and produces a series of reports summarizing the overall activity on the recording and highlighting significant clinical events. The system provides for review of the automated analysis and for a qualified user to make editing changes to the automated results.

The Cardiology Workstation can also receive input from an analog-based cassette tape ambulatory recorder and an infrared serial link, as well as from the SpaceLabs PCMS monitoring network to provide for the collection,

review, editing, printing and archiving of waveform data records.

**6. Comparison of Technological Characteristics**

We consider the ECG Analysis System to be substantially equivalent to systems currently marketed by both SpaceLabs Medical and Zymed Corporation. The design, components, storage technology and energy source are similar to its predicate devices.

All systems provide a means for the collection, display, review, editing, analysis, printing, and archival of patient ECG data. The only significant differences between the SpaceLabs Medical ECG Analysis System and the comparable Zymed systems are in some of the feature sets of the two systems. The Zymed Workstation provides additional capabilities for the collection of ambulatory blood pressure measurements and the 12-lead reconstruction from 3 channel ambulatory. The SpaceLabs Medical Cardiology Workstation has the capability for receiving input from analog cassette ambulatory recording tapes and via an IR Serial Link or Ethernet interface in addition to digital memory cards.

**7. Testing**

The SpaceLabs Medical ECG Analysis System 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. The ECG Analysis system meets the specified clinical output data requirements of the ANSI/AAMI EC38-1994 specification for ambulatory electrocardiography. Standard databases have been used for automated ECG algorithm verification testing. 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 ECG Analysis System is as safe and effective as the predicate devices and raises no new issues.