

AUG 21 1996



K960321

Technology at Work

Section 2: Safety and Effectiveness Summary (510K Summary)

A. Trade Name: CardioCath Catheterization Lab System

B. Common Name: Cardiac Cath Lab System

C. Establishment Registration Number: 1643488

D. Address of Manufacturing Site:

Prucka Engineering, Inc.
8050 El Rio
Houston, Texas 77054
713-746-1000
713-747-8451 Fax

E. Classification:

The CardioCath system is a multi-channel pressure and electrocardiograph system that digitizes, and stores pressure and electrical signal information on magnetic media. Prucka Engineering, Inc. considers the CardioCath system to be a Class II device within FDA classification 74 DPS. The CardioCath is designed to comply with FDA, UL 2601, IEC 601-1 and AAMI guidelines for patient leakage current.

F: Predicate Devices:

Prucka Engineering believes the CardioLab Catheterization Lab System to be substantially equivalent to several devices currently in commercial distribution, including Quinton Q-Cath Computerized Cath Lab Recording System. The device is manufactured by:

Quinton Instrument Co.
2121 Terry Avenue
Seattle, WA 98121

Marquette Electronics Inc. also manufactures and distributes a computerized cath lab recording system called MAC-Lab. This product is also substantially equivalent to the PECA system. The device is manufactured by:

Marquette Electronics, Inc.

8200 W. Tower Ave.
Milwaukee, Wisconsin 53223

Similar Characteristics:

Both the Quinton Q-cath system and Marquette MAC-Lab system contain similar physical characteristics and specifications as the CardioCath system. All of the systems begin with a data acquisition unit which connects to the patient to collect both electrical ECG and intracardiac signals as well as pressure waveforms acquired by various pressure transducers. The data is digitized and stored in a computer which displays the data on video monitors. The systems allow the user to archive, perform signal measurements and to print out signals on both continuous paper recorder or on a laser printer.

All the systems provide isolation of biopotential signals from the patient to ground, high impedance inputs, high gain and variable filtering capabilities required for measuring bioelectric potentials. All systems provide isolation, conditioning and amplifications of electrical signals from strain gage blood pressure transducers.

All systems are microprocessor based and feature graphical user interfaces. The systems allow the user to acquire, display, measure and printout various biopotential waveforms.

System Differences:

Marquette Electronics, Inc. MAC-Lab. The CardioLab system uses 21" monitors instead of 16" monitors. The maximum resolution of the monitors for the CardioCath system is 1600 x 1280. The resolution on the MAC-Lab is 800 x 600. The MAC-Lab system records from up to 4 ECG, 4 Blood Pressure (BP), and 4 BP Mean signals simultaneous. The CardioCath system will record up to 32 signals simultaneously. The user may select a combination of signals from a 12 lead ECG, 6 blood pressure channels, 6 BP mean channels, 4 high level DC signals, and 32 intracardiac signals, for a total of 32 signals to be acquired simultaneously. The MAC-Lab system uses a Motorola 68000 and an Intel 80286 based computer, while the CardioCath system uses an Intel 80486 based system. The MAC-Lab system archives data on floppy disks whereas the CardioCath system archives data on optical disk.

Quinton Instruments Q-Cath. The Q-Cath system uses either 16" or 14" color monitors whereas the CardioCath system uses 21" monitors. The Q-Cath system can record up to 6 channels simultaneously from 3 ECG, 4 BP, 4 BP mean, 4 dP/dt, 3 intracardiac and 2 High Level DC signals. The CardioCath system can record up to 32 signals simultaneous where the user can choose from a 12 lead ECG, 6 BP, 6 BP Mean, 4 High Level DC signals, and 32 intracardiac signals. The Q-Cath system archives data on floppy disks whereas the CardioCath system archives data on optical disk.

G: System Description and Intended Use

) System Configuration: The CardioCath system is a data acquisition unit which connects to the patient to collect both electrical ECG and intracardiac signals as well as pressure waveforms acquired by various pressure transducers. The data is digitized and stored in a computer which displays the data on video monitors. The system allows the user to archive, perform signal measurements and to print out signals on both continuous paper recorder or on a laser printer.

Intended Use: The system is used in a cardiac catheterization laboratory where ECG, intracardiac signals, and pressure recordings need to be recorded from a patient. 

Function: The system provides isolation of biopotential signals from the patient to ground, high impedance inputs, high gain and variable filtering capabilities required for measuring bioelectric potentials. The system provides isolation, conditioning and amplifications of electrical signals from strain gage blood pressure transducers.

Design: The system incorporates defibrillation protection and is designed to comply with IEC 601-1 and U.L. 544 electrical safety standards.

Operation: The system is microprocessor based and feature graphical user interfaces. The system allows the user to acquire, display, measure and printout various biopotential waveforms.

) H: Safety Standards

The CardioCath system was designed to meet IEC 601-1 which applies to the safety of medical electrical equipment and the reliable operation where it is connected with safety and IEC 601-2-27 which applies to the particular safety requirements for electrocardiographic (ECG) monitoring equipment and IEC 601-2-34 which applies to the particular safety requirements for invasive pressure monitoring equipment.

IEC 601-1 covers the following safety aspects of the device:

- Environmental conditions during transportation and storage, operation and use of the power supply.

- Enclosures and protective covers

- Insulation and protective impedances

- Protective earthing, functional earthing and potential equalization.

- Continuous leakage currents and patient auxiliary currents

- Dielectric strength

- Mechanical strength

- Moving parts

- Stability in Normal Use

- Expelled Parts

- Protection against excessive temperatures

- Overflow, spillage, leakage, humidity, ingress of liquids and cleaning.

- Interruption of the power supply

- Abnormal operation and fault conditions

IEC 601-2-27 covers the following safety aspects of the device as they relate to ECG monitoring:

- Protection against the effects of a cardiac defibrillator discharge
- Continuous leakage currents and patient auxiliary currents
- Dielectric strength
- Accuracy of operating data and protection against hazardous output

IEC 601-2-34 covers the following safety aspects of the device as they relate to the invasive blood pressure monitoring:

- Protection against the effects of a cardiac defibrillator discharge
- Continuous leakage currents and patient auxiliary currents
- Dielectric strength
- Mechanical strength
- Accuracy of operating data and protection against hazardous output

The equipment has been tested and certified to meet the above specifications by SEMKO which is an Inchcape Testing Services Company.