K 96 0 382

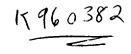## SUMMARY OF SAFETY AND EFFECTIVENESS

K960382

I.   INTRODUCTION

The KODAK Digital Science Medical Image Manager is an extension of the KODAK Health Sciences Imagelink System with the intended use to be used as a network gateway to a host of image management and printing devices.

II.   GENERAL INFORMATION

APR 1 7 1996

Name of Manufacture:
Eastman Kodak Company
Health Sciences Division
18325 Waterview Parkway
Dallas, Texas   75252-8026

Establishment Registration Number:

Device Name:

KODAK Digital Science Medical Image Manager

Device Classification:

Class 1 Device

III.   THE DEVICE

The general hardware configuration of the KODAK digital Science Medical Imager contains the following major components:
- Power Supply
- Main System Circuit Board
- Hard Dick
- Internal Removable Media
- Keypad

Optional Accessories:
- Keypad Accessories
    - Mini-keypad
    - Microphone
    - Modality Store Connection
    - Keyboard
- Bar Code Reader
- Magnetic Stripe Reader

IV. INDICATIONS FOR USE

The KODAK Digital Science Medical Image Manager will provide network access for both point -to - point and network capable image and information sources. The Image Manager will provide a value added service to point - to - point devices by adding services including routing to multiple destinations and access to multiple printers. However, evaluation of soft copy or hard copy output provides adequate opportunity for competent human intervention. PACS are not represented to be used in supporting or sustaining human life, nor do they represent a potential for unreasonable risk of illness or injury.

V. COMPARISON OF FEATURES

| | KODAK EKTASCAN IMAGELINK Ultrasound System | KODAK DIGITAL SCIENCE Remote Network Interface |

General

K-Number	K-931551	This 510(k)
Power Requirements	90-132VAC/47-63Hz 180-264VAC/47-63Hz	100VAC +/-10%,50/60 Hz (+/-2%)250w 120VAC +/-10%,60Hz (+/-2%)250w 220VAC +/-10%,50/60 Hz (+/-2%)250w 240VAC +/-10%,50/60 Hz (+/-2%)250w
Environmental	15-35 degrees C / 15-90% RH non-condensing	41-95 degrees F / 15-80% RH non-condensing

Acquisition Unit

Removable Disk	2.5" Hard Disk	3.5" Floppy, 3.5" Magneto Optical (MOD)
Disk Storage Capacity	30,40,60,80,105 Mbytes	1-4 GBytes
Network Capability	Ethernet	Ethernet
Video Image Inputs	Monochrome: RS-170/CCIR Red,Green,Blue (RGB)	Monochrome: RS-170/CCIR Red,Green,Blue (RGB), CINE Loop, Motion Video
Digital Image Inputs	None	8 and 12 Bit Digital Images in UBMED Format
Serial Control Inputs	None	RS-232, RS-422
Image Capture Time	1/30 second (.25MB)	Grayscale Video: .2s (1MB) Color Video: .25s(1MB) 8-Bit Digital: .2s (1MB)
Image Store Time	Grayscale Video: <2 seconds (.25MB) Color Video: <5 seconds (.75MB)	Grayscale Video: .5s (1MB) Color Video: 1.5s (3MB) 8-Bit Digital: .5s (1MB)

Reader Unit

Inputs	Removable Disk Cartridge Ethernet - ACR/NEMA Format	3.5" Floppy, 3.5" Magneto Optical Ethernet - DICOM Format, HIS/RIS Interface
Outputs	SCSI, Video, RS-485, RS-422, RS-232	Ethernet, RS-485, High Speed Optical, Modem, ATM, SCSI
Image Presentation	1,2,4,6,8,9,12,15,16,20,24,30,35	1,2,4,6,8,9,12,15,16,20,24,30,35,slide