

NOV 14 1996

K961739

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

I. **DATE PREPARED:** April 30, 1996
Revised: November 11, 1996

II. **SUBMITTER:**

Eastman Kodak Company
Health Imaging Division
18325 Waterview Parkway
Dallas, Texas 75252-8026

III. **CONTACT PERSON:**

Nancy Butcher
Regulatory Affairs
(214) 454-1417

IV. **DEVICE NAME:**

Trade Name **KODAK Digital Science Medical Modality Acquisition Unit (K961739)**

Common Name **Picture Archiving and Communications Systems (PACS) Components**

V. **DEVICE CLASSIFICATION**

FDA has classified the predicate device as Regulatory Class II under 21 CFR 892.1750.

VI. **PREDICATE DEVICE:**

KODAK Ektascan Imagelink System

VII. **DESCRIPTION OF DEVICE:**

The KODAK Ektascan Imagelink System [KEIS] is composed of components common to all image management systems for image acquisition, printing, review, archive/retrieval, and communications. These components can be combined into customized solutions for the management of diagnostic image information.. Evaluation of soft and or hard copy output provides adequate opportunity for competent human intervention.

VIII. INDICATIONS FOR USE:

The KODAK Ektascan Imagelink System (KEIS) is a DICOM conformer product designed for use within a Picture Archiving and Communication System (PACS).

The KODAK Ektascan Imagelink System is composed of two major components, the KODAK Digital Science Medical Modality Acquisition Unit and the KODAK Digital Science Medical Printer Interface Unit. These systems can exit together or independently on a network.

V. COMPARISON OF FEATURES:

SIDE-BY-SIDE COMPARISON TABLE

Characteristics	KODAK Digital Science Medical Modality Acquisition Unit and Printer Interface Unit	KODAK Ektascan Imagelink System
Knumber	this submission	K931551
GENERAL		
Advertised use	Productivity improvement, eliminate film cassettes and darkroom processing, eliminate need to sterilize film cassettes	Productivity improvement, eliminate film cassettes and darkroom processing, eliminate need to sterilize film cassettes
Input modalities advertised	C-Arm, Digital Subtraction Angiography, Nuclear Medicine, Ultrasound, and other video modalities.	C-Arm, Digital Subtraction Angiography, Nuclear Medicine, and Ultrasound
Power requirements	90-132vac/47-63Hz 180-264vac/47-63Hz	90-132vac/47-63Hz 180-264vac/47-63Hz
Environmental	4-45 degrees C/15-90% RH non-condensing	4-45 degrees C/15-90% RH non-condensing
Acquisition Unit		
Removable Disk	2.5" Hard Drive	2.5" Hard Drive
Disk Storage Capacity	105, 30, 60, 80 Mbytes	30, 60 Mbytes
Network Capability	Ethernet	Ethernet
Video Inputs	Monochrome: RS-170/CCIR; Red, Green, Blue (RGB)	Monochrome: RS-170/CCIR; Red, Green, Blue (RGB)
Image Capture Time	1/30 second	1/30 second
Image Store Time	Less than 1 second	Less than 1 Second
Printer Interface Unit		
Inputs	Removable Disk Cartridge, Ethernet, DICOM v3.0 format (ACR_NEMA)	Removable Disk Cartridge, Ethernet, DICOM v3.0 format (ACR_NEMA)
Outputs	SCSI, Video, RS-485, RS-422, RS-232	SCSI, Video, RS-485, RS-422, RS-232
Image Presentation	1,2,4,6,8,9,12,15,16,24,35 images per frame, plus slides	1,2,4,6,8,9,12,15,16,24,35 images per frame, plus slides