

NOV 14 1996

K961740

**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  
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Dallas, Texas 75252-8026

III. **CONTACT PERSON:**

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IV **DEVICE NAME:**

Trade Name           KODAK Digital Science Medical Printer Interface Unit (K961740)

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 conformant 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 exist together or independently on a network.

**V. COMPARISON OF FEATURES:**

**SIDE-BY-SIDE COMPARISON TABLE**

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