

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

I. DATE PREPARED: October 28, 1997

II. SUBMITTER:

JAN 21 1998

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 Quality Control Workstation

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 Quality Control Workstation

VII. COMPARISON OF FEATURES:

SIDE-BY-SIDE COMPARISON TABLE

Characteristics	KODAK Digital Science Quality Control Workstation	KODAK Ektascan Imagelink Quality Control Workstation
Knumber	this submission	K923270
GENERAL		
Advertised use	Image enhancement which allows for the proper display of the images for diagnostic purposes New Image Processing Library	Productivity improvement, eliminate film cassettes and darkroom processing, eliminate need to sterilize film cassettes
Hardware 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	2.0GB Boot Disk	2.5" Hard Drive
Disk Storage Capacity	4GB, 8GB, 12GB, 16GB	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

VIII. DESCRIPTION OF DEVICE:

Kodak's Quality Control Workstation is a Sun Microsystems based workstation for the display, printing, and manipulation of medical images. The Quality Control Workstation is designed with an ethernet interface to interface with other Kodak products or digital systems using ACR/NEMA compatible interfaces and or DICOM.

The patient is not connected to a Quality Control Workstation. The Quality Control Workstation does not control, monitor or affect any equipment that is directly involved with a patient.

The Quality Control Workstation is attached via a SCSI cable to a KODAK Digital Science Storage Phosphor Reader (K913354). The KDSSPR is not in direct contact with a patient. Therefore, the patient is electrically isolated from the Quality Control Workstation equipment and any conceivable electrical failure would not affect the patient.

The Quality Control Workstation does not manipulate data on which a primary diagnosis or finding may be based except to enhance portions of images for a clearer view.

Images displayed on the Quality Control Workstation will not be used for primary diagnosis. Images outputted from the Quality Control Workstation to a laser printer or workstations on the ethernet will be used for primary diagnosis. The evaluation of the hard copy output provides adequate opportunity for competent human intervention.

The primary function of the Quality Control Workstation is to display with no corruption of the image information. The level of concern associated with the function is minor, as failures or latent design flaws would not be expected to result in injury to the patient.

IX. The Device

The general hardware configuration of the Quality Control Workstation contains the following major components:

- Sun Microsystems Desktop Workstation with
 - SCSI (Small Computer System Interface)
 - ethernet interface
 - Floppy disk drive/ CD ROM drive
- Gray Scale Display
- External Hard Disk Multipack
- Tape Drive
- Bar code printer
- Uninterrupted Power Supply (UPS)

X. Indication for Use

The Quality Control Workstation allows radiologist technicians to enter patient information and/or correct erroneous patient information, exam information, and if necessary, the image look and/or image orientation. It allows them to route it to different locations to give greater flexibility to physicians in analyzing patient images.

XI. Methodology

The Quality Control Workstation acquires images from phosphor readers and attaches patient records for transmission to other systems.

The Quality Control Workstation can be use in two modes: pass through or manual mode. In pass through mode, an exam is processed at the Quality Control Workstation and then routed directly to its destination. In manual mode, a user must verify the image and Patient and exam information before releasing it to its destination.

The image enhancement which allows for the proper display of the images for diagnostic purposes is performed by adaptive unsharp masking processing and tonescaling.

It uses computed or user-specified values. This is a non-destructive image processing routine to the raw image. Because this routine modifies the original data, a copy of the original data is kept until the image has been approved and forwarded to a destination. The data remains at the Quality Control Workstation for a hospital configurable time before it is deleted.

For each raw image, the Quality Control Workstation generates at least one enhanced version. The number of enhanced versions is dependent on the type of exam and the user can create versions as needed. The raw data is never changed.

The Quality Control Workstation is a network-orientated workstation supporting the ACR/NEMA and or DICOM format over TCP/IP.

Images may be manipulated using a mouse/trackball for such functions as rotating and flipping.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 21 1998

Nancy Butcher
Eastman Kodak Company
Health Imaging Division
18325 Waterview Parkway
Dallas, Texas 75252-8206

Re: K974107
Kodak Digital Science Quality Control Workstation (QCV)
Dated: October 30, 1997
Received: October 31, 1997
Regulatory class: Unclassified
Procode: 90 LMD

Dear Ms. Butcher:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

K974107

Device Name: KODAK Digital Science Quality Control Workstation

INDICATION FOR USE:

The Quality Control Workstation (QCW) is a networked-oriented workstation supporting the KODAK Digital Science System standard network (ACR/NEMA and/or DICOM over TCP/IP).

The Quality Control Workstation allows radiologist technicians to enter patient information and/or correct erroneous patient information, exam information, and if necessary, the image look and/or image orientation. It allows them to route it to different locations to give greater flexibility to physicians in analyzing patient images.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDR., Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

David G. Johnson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974107