510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K980118

I. DATE PREPARED: December 1, 1997

MAR 17 1998

II. SUBMITTER:

Eastman Kodak Company
Health Imaging Division
901 Elmgrove Road
Rochester, New York 14653

III. CONTACT PERSON:

Nancy Butcher
Regulatory Affairs
(214) 454-1417

IV DEVICE NAME:

Trade Name KODAK Oncology Image Manager (OIM)

V DEVICE CLASSIFICATION

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

VI. PREDICATE DEVICE:

IMPAC, IMAGErt, IMAGE Management System

VII. COMPARISON OF FEATURES:

Characteristics	KODAK Digital Science Oncology Image Manager	IMPAC, IMAGErt, Image Management System
Knumber	this submission	K942346
GENERAL		
Advertised use	An acquisition, management, distribution and archiving system, PACS device.	A computerized image management system.
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
Hardware Description	Server, Workcenter, Review Computer	Viewstations, Maintenance, Namer
Network Capability	Ethernet, Internet, Intranet	Ethernet, Internet, Interanet
Data Type	Image, Text, Patient Information	Image, Text, Patient Information
Input Sources	Diagnostic interface, Networked interfaces, DICOM images, Removable media, Digital cameras	Diagnostic interface, Networked interfaces, DICOM images, Removable media
Output Devices	CD, Printers, offline storage devices	CD, Printers, offline storage devices
Operating System	Windows NT	PC Compatible
Image Preview	yes	yes
Open Case Preview	yes	yes
Receive Images from other systems	yes	yes
Retrieve Images from other systems	yes	yes
Patient Demographic Information	yes	yes
Acquire Radiographic Films from Film Digitizer	yes	yes
Portable patient records	yes	yes

VIII. DESCRIPTION OF DEVICE:

KODAK Oncology Image Manager is designed to archive patient information and images gathered as the patient progresses through cancer treatment. The consolidated information and images can be reviewed as treatment progresses by onocologist and nurses..

IX. THE DEVICE

The general hardware configuration of the KODAK Oncology Image Manager contains the following major components:

-Touch screen Monitor
-Central Processing Unit (CPU)
-Film and Document scanners
-CD-ROM writer and reader

X. INDICATION FOR USE

The KODAK Oncology Image manager (OIM) is a picture Archiving and Communications System (PACS) which acquires, communicates, stores, and displays images, including radiographic images and patient data connected with oncology treatment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 1998

Nancy Butcher
Regulatory Affairs Specialist
Eastman Kodak Company
Health Imaging Division
18325 Waterview Parkway
Dallas, Texas 75252

Re: K980118
Kodak Digital Science Oncology Image Manager
Dated: December 1, 1997
Received: January 13, 1998
Regulatory class: Unclassified
Procode: 90 LLZ

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 requirements, 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/dsma/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): K980118
Device Name: KODAK Oncology Image manager (OIM)

INDICATION FOR USE:

The KODAK Oncology Image Manager (OIM) a Picture Archiving and Communications System (PACS) which acquires, communicates, stores, and displays images, including radiographic images and patient data connected with oncology treatment.

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

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

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CRF 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K980118