AUG 1 0 2001

Attachment 6

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K012155

1. Submitter name, address, contact

Eastman Kodak Company.
343 State Street
Rochester, New York 14650
(716) 724-4795

Contact Person: Anne Zavertnik

2. Preparation date

Date 510(k) prepared: July 10, 2001

3. Device name

Trade or Proprietary Name:	Kodak Radiation Oncology Software / for ACR systems
Common Name:	DICOM Client
Classification Name:	PACS under 21 CFR 892.2050

4. Predicate device

The Kodak Radiation Oncology Software is substantially equivalent to the DI-2000 DICOM Client (K980213, March 17, 1998), formerly owned by Lumisys, Inc.

Continued on next page

510(k) Summary, Continued

5. Device description	The Kodak Radiation Oncology Software / for ACR systems enables digitization of computed radiography exposed phosphor plates for acquiring portal (localization and verification) images and simulation images. The device enables capture, processing, viewing and transmission of DICOM 3.0 compliant images for printing, archiving or display. Image review tools are included that enable the user to adjust, magnify, and annotate the images. The Kodak Radiation Oncology Software / for ACR systems is dedicated specifically for use with Kodak ACR products.
6. Device intended use	Kodak Radiation Oncology Software / for ACR systems utilizes a scanner and software interface to digitize computed radiography exposed phosphor plates. Kodak Radiation Oncology Software / for ACR systems is DICOM 3.0 compliant radiological digitization application. Kodak Radiation Oncology Software / for ACR systems is enables the user to autoarchive lossless or lossy compressed images locally or at a remote archive site. Supports DICOM 3.0 Query and Retrieve Service Class
7. Comparison to predicate device	The intended use of the Kodak Radiation Oncology Software is the same as the intended use as previously cleared for DI-2000 DICOM CLIENT software, (K980213, March 17, 1998), in that it supports digitization of phosphor plates exposed in computed radiography. The Kodak Radiation Oncology Software narrows the focus from the general radiology applications to radiation therapy applications. While the Kodak Radiation Oncology Software enables the digitization of phosphor plates, it will not enable digitization of radiology films on film digitizers as the DI-2000 DICOM CLIENT does. Table 1 lists a comparison of characteristics of the Kodak Radiation Oncology Software and the predicate device.

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7. Comparison to predicate device, Continued

Table 1

Feature	Kodak Radiation Oncology Software	Predicate device
Acquires portal localization, verification and simulation images	Y	N
Patient Information modification	Y	Y
Delete Patient Information	Y	Y
Annotate DICOM images	Y	N
Automatic and dynamic window and level controls	Y	Y
Automatic output of DICOM 3.0 images	Y	Y
Group send to multiple locations	Y	Y
Supports full 12 bit grayscale data	Y	Y
Image Flip	Y	Y
Image rotation	Y	Y
JPEG Lossless, Lossy, Enhanced compression	Y	Y
Print DICOM Image	Y	Y
Windows Print	Y	Y
Quality Assurance function	Y	Y
LAN/WAN Communication	Y	Y

8. Conclusions The information presented in the pre-market notification demonstrates that the performance of the Kodak Radiation Oncology Software is substantially equivalent to the cleared predicate device and provides a reasonable assurance that the Kodak Radiation Oncology Software is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2001

Ms. Anne Zavertnik
Regulatory Affairs Manager
Eastman Kodak Company
343 State Street
ROCHESTER NEW YORK 14650

Re: K012155
Kodak Radiation Oncology Software for ACR Systems
Dated: July 10, 2001
Received: July 11, 2001
Regulatory Class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Ms. Zavertnik:

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 legally marketed predicate 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) 594-4639. 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" (21CFR 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Attachment 1

Statement of Intended Use

510(k) Number (if known): K012155

Device Name: Kodak Radiation Oncology Software / for ACR systems

Indications for Use:

Kodak Radiation Oncology Software / for ACR systems is intended to utilize a scanner and software interface to digitize computed radiography exposed phosphor plates.

Kodak Radiation Oncology Software / for ACR systems is DICOM 3.0 compliant radiological digitization application.

Kodak Radiation Oncology Software / for ACR systems is enables the user to autoarchive lossless or lossy compressed images locally or at a remote archive site. Supports DICOM 3.0 Query and Retrieve Service Class.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012155

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)