MAY 2 9 2003

## 6.1 510(k) Summary

### 1. Company Identification

Eastman Kodak Company
343 State Street
Rochester, NY 14650

### 2. Contact Person

Linda J. Moore, Dir.of Regulatory Affairs, HCIS Products
Eastman Kodak Health Imaging
47315 Mission Falls Ct.
Fremont, CA 94539
510-770-5456
Fax. 510-770-5544
Linda.j.moore@kodak.com

### 3. 510(k) Summary Preparation Date

March 7, 2003

### 4. Device Name

Kodak DirectView PACS/Image Management Systems

### 5. Device Classification

Class II

### 6. Intended Use/Device Description

Eastman Kodak DirectView PACS/Image Management System(DV PACS) intended use is to provide completely scaleable image/data management solutions for hospital and related institutions/sites including, at a minimum, local to wide area primary diagnostic workstations to enterprise storage centers. DV PACS also provides services that will allow remote sites to have access to diagnostic image/patient data through industry standard interfaces, including web browsers supported by Eastman Kodak and other's predicate devices. DV PACS is designed using an open architecture that allows various proprietary and off the shelf (OTF) software integrated with OTF hardware components to be configured to meet the user's specific needs. Using DICOM and other industry standards, DirectView PACS archives/ distributes/retrieves and displays images and data from all hospital modalities including but not limited to, CT, MRI, Ultrasound

(US), CR, DR, Nuclear Medicine (NM), mammography, cardio systems, digitized X-ray films, digital angiography, and fluoroscopy as well as all hospital/radiology information systems.

## 7. Substantial Equivalence Summary

The DirectView PACS/Image Management System is substantially equivalent in design and intended use to diagnostic radiological workstations, PACS and image management systems as substantiated in the feature comparison. The comparison listed in Section 3.3 clearly demonstrates that DirectView PACS/Image Management System is substantially equivalent in all areas such as functionality, user/software features, hardware components and connectivity. Although, the comparison only lists DirectView PACS equivalence to its predecessors, AccuRad and Archive Manager, the stated indications for use, listed on the comparison, does show substantial equivalence to other manufacturer's industry standard PACS/image management systems. Therefore, DirectView PACS raises no new issues of safety or effectiveness from its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 9 2003

Ms. Linda J. Moore
Director, Regulatory Affairs,
HCIS Products
Eastman Kodak Company
47315 Mission Falls Ct.
FREMONT CA 94539

Re: K030781
Trade/Device Name: Kodak DirectView PACS/Image Management System
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: March 7, 2003
Received: March 11, 2003

Dear Ms. Moore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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

# 6.2 FDA Indications for Use

510K # K030781

Device Name: Kodak DirectView PACS/Image Management System

Indications for Use: The Kodak DirectView PACS is an image management system whose intended use is to provide completely scaleable local and wide area PACS solutions for hospital and related institutions/sites, which will archive/ distribute/ retrieve and display images and data from all hospital modalities and information systems.

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Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over – The – Counter _____
(Per 21 CFR 801.109)

David A. Lieberman
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030781