SEP 11 1997

7.0 Safety and Effectiveness Information

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS K972380

I. DATE PREPARED: June 23, 1996

II. SUBMITTER:

Eastman Kodak Company
Health Imaging Division
18325 Waterview Parkway
Dallas, Texas 75252-8026

III. CONTACT PERSON:

Stan E. Tillman
Director, Regulatory Affairs
Health Imaging Division, Dallas
(972) 454-1642

IV. DEVICE NAME:

Trade Name - KODAK DIGITAL SCIENCE™ (KDS) Medical Image and Information Library (MIIL)

Common Name - PACS Storage Device (Archive)

V. DEVICE CLASSIFICATION

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

VI. PREDICATE DEVICE

Kodak Digital Science Medical Image and Information Library--K960981

VII. DESCRIPTION OF DEVICE

The system consists of three main components: 1) the host CPU (a Sun SPARCstation 5, SPARCstation 20, or UltraSparc) with pre-installed proprietary software, 2) the magnetic cache, a Sun SPARC storage Redundant Array of Inexpensive Disks (RAID) subsystem, and 3) a KODAK DIGITAL SCIENCE ADL 150 writeable CD jukebox or a Digital Linear Tape (DLT) library. The RAID subsystem, combined with either the CD jukebox or DLT library, are managed by a hierarchical storage library that presents these two subsystems to the system software running on the host CPU as a single, very large filesystem. The power supply provides power to operate the unit from a line voltage for 100, 120, 220, or 240 VAC, 50/60 Hz.

VIII. INDICATIONS FOR USE

The KODAK DIGITAL SCIENCE (KDS) Medical Image and Information Library is a DICOM conformant archival product designed for use within a Picture Archiving and Communication System (PACS). The system utilizes a prefetching algorithm to facilitate fast access to previous imagery.

V. COMPARISON OF FEATURES

K-number	This 510(k)	K960981
Range of Storage	12 GB - 20 TB	8 GB to 216 GB
Type of Interface	SCSI	SCSI
Type of Media	5.25" CD-Recordable or Digital Linear Tape (DLT)	5.25" CD-Recordable
Jukebox, Maximum	Yes, 150-CD or 588 DLT Cartridges	Yes, 150-CD
Compression	Yes, lossless 2:1 or lossy to 50:1	Yes, lossless 2:1
DICOM Conformant	Yes, Native	Yes, Native
HIS/RIS Interface	Yes	Yes
Host Platform	Sun	Sun
Database Structure	Distributed	Distributed

6/97

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 1997

Stan E. Tillman
Director, Regulatory Affairs
Eastman Kodak Company
Health Imaging Division
Medical Imaging Systems
18325 Waterview Parkway
Dallas, Texas 75252

Re: K972380
"Kodak Digital Science™ Medical Image Archive"
Dated: June 23, 1997
Received: June 26, 1997
Regulatory class: Unclassified
Procode: 90 LMB

Dear Mr. Tillman:

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): K972380

Device Name: Kodak Digital Science™ Medical Image and Information Library (MIIL)

INDICATION FOR USE:

DICOM conformant archival product (storage library) designed for use within a Picture Archiving and Communications System (PACS).

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

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X 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 K972380