JUN 18 1998

K981053

SUMMARY OF SAFETY AND EFFECTIVENESS

I. DATE PREPARED: March 17, 1998

II. SUBMITTER

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

III. CONTACT PERSON

Robert M. Wolfarth
Regulatory Affairs Specialist
(972) 454-1466

IV DEVICE NAME

Trade Name: Kodak Digital Science™ (KDS) ImageVIEW

Common Name: Picture Archiving and Communications Systems (PACS) Components

V DEVICE CLASSIFICATION

The FDA has classified the predicate device as Unclassified (Product Code 90 LMD) under 21 CFR 892.1750.

VI. PREDICATE DEVICE

Trade Name: MediSurf, currently marketed in the United States by Algotec Systems, Ltd. (K971347)

VII. DESCRIPTION OF DEVICE

The Kodak Digital Science™ (KDS) ImageVIEW family of products is designed to facilitate the distribution of images from standard DICOM storage devices within the radiology department and provide controlled Internet access to images stored on DICOM storage devices. Browser extensions will allow dynamic viewing and manipulation of these medical images. This family of products will initially provide image viewing and referral printing functionality to referring and clinical physicians, but will be extended to provide diagnostic viewing and printing functionality for radiology use. They will also provide intelligent management of images and information to facilitate productivity enhancements for its users. ImageVIEWs are not represented to be of use in supporting or sustaining human life, nor do they represent a potential of unreasonable risk of illness or injury.

VIII. INDICATIONS FOR USE

The Kodak Digital Science™ (KDS) ImageVIEW is a network-oriented client/server type PACS system for the distribution, viewing, and printing of medical images at distributed locations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 1998

Robert Wolfarth
Regulatory Affairs Specialist
Eastman Kodak Company
18325 Waterview Parkway
Dallas, Texas 75252

Re: K981053
Kodak Digital Science (KDS) ImageView
Dated: March 17, 1998
Received: March 23, 1998
Regulatory class: II
21 CFR 892.2050/Procode: 90 LMD

Dear Mr. Wolfarth:

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): K981053

Device Name: Kodak Digital Science™ (KDS) ImageVIEW

INDICATION FOR USE:

The Kodak Digital Science™ (KDS) ImageVIEW is a network-oriented client/server type PACS system for the distribution, viewing, and printing of medical images at distributed locations.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981053