K033821
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Section B1

510(k) Summary

November 26, 2003

Eastman Kodak Company
343 State Street
Rochester NY 14650

Contact: Stephen Slavens
1 Imation Way, 304-3B-61
Oakdale, MN 55128
Phone: 651-393-1395
FAX: 651-393-1440

Device:

Trade name:	KODAK DRYVIEW 8900 Laser Imager with Mammography Accessory
Common name:	Laser Printer
Classification name:	Medical Image Hardcopy Device 21 CFR 892.2040

Predicate device: Kodak DRYVIEW 8610 Laser Imager/ for Mammography (K002146)

Description And Intended Use of Device:

The KODAK DRYVIEW 8900 Laser Imager Mammography Accessory's intended use is as a hard copy device for output from imaging source modalities for use in medical imaging diagnosis and referral. Electronic image information signals are managed in the 8900 and transformed optically to expose KODAK DRYVIEW imaging media. The system is intended for use with a variety of digital modalities, including, but not limited to CR, DR, CT, MR, Ultrasound, Nuclear Medicine, FFDM etc. for diagnostic use by medical radiologists and communications to referring physicians and their patients.

Technological Characteristics:

The subject device and predicate devices use the same technical design base. The printers receive image data from the modality. User control is performed directly by the modality or through the host control. KODAK DRYVIEW imaging media is removed from a daylight cartridge and transported to the laser imaging station. Image data and media merge at the laser station and the film is scanned. The exposed media is transported through the integrated processor and exits the printer.

Software is used to control the image management and machine functions. AIQC (Automated Image Quality Control) matches printing power with film characteristics to provide consistently high image quality.

Performance Data:

Safety and effectiveness are assured via meeting voluntary standards, including: DICOM, SMPTE, UL 60950, IEC 60601-1-1, IEC 60825-1, ISO 12207, and ISO 14971.

Conclusion:

The subject device, like the predicate, has no patient contact. The devices also do not control, monitor or otherwise affect any devices directly connected to or affecting the patient. Medical personnel review images displayed by the subject device and its predicates. This offers ample opportunity for competent human intervention in case of a malfunction or other failure.

The subject KODAK DRYVIEW 8900 Laser Imager with Mammography Accessory and predicate device KODAK DRYVIEW 8610 Laser Imager for mammography have both been designed to the equivalent safety standards. As with this predicate device, a test pattern generator and automatic image quality control (AIQC) system are incorporated to assure consistency between input signals and output density. Both are high resolution printers with incorporated test patterns to assist in MQSA quality assurance testing.

Eastman Kodak therefore concludes that the KODAK DRYVIEW 8900 Laser Imager Mammography Accessory is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 0 2004

Mr. Stephen Slavens
Regulatory Affairs Director
Eastman Kodak Health Imaging Group
1 Image Way 304-3B-61
OAKDALE MN 55127

Re: K033821
Trade/Device Name: KODAK DRYVIEW 8900 Laser Imager with Mammography Accessory
Regulation Number: 21 CFR 892.2040
Regulation Name: Medical image hardcopy device
Regulatory Class: II
Product Code: 90 LMC
Dated: December 4, 2003
Received: December 9, 2003

Dear Mr. Slavens:

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 such 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 Section 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 the 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" (21CFR Part 807.97) you may obtain. 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

Section B2

Statement of Indications for Use:

510(K) Number (if known): K033821

Device Name: KODAK DRYVIEW 8900 Laser Imager with Mammography Accessory

Indications for Use:

The KODAK DRYVIEW 8900 Laser Imager with Mammography Accessory is intended to provide high-resolution hard copy images from digital imaging source output signals. The device is intended for use with KODAK DRYVIEW DVM film for use with a variety of digital modalities, including, but not limited to, CR (Computed Radiology), DR (Digital Radiology) and FFDM (Full Field Digital mammography). The images are to be used for medical diagnosis medical and referring physicians and their patients.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use_____

(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033821