K042159

SEP 2 4 2004

Section B1

510(k) Summary

September 14, 2004

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 Color Medical Imager 1000
Common name:	KPRO 8500 Color Printer
Classification name:	Medical Image Hardcopy Device 21 CFR 892.2040
Predicate device:	Codonics EP-1000 Medical Color dry imager (K030690)

Description And Intended Use of Device:

The KODAK Color Medical Imager 1000 is intended for use as a hard copy device for output from imaging source modalities used in medical imaging diagnosis and referral. Electronic image information signals are managed in the KODAK Color Medical Imager 1000 and transformed to heat a color donor ribbon and drive color dyes to a receptor sheet using thermal dye sublimation technology.

The Intended Use of the Kodak Color Medical Imager 1000 series medical printers is as thermal print engines intended to produce continuous tone photographic quality hard copy output with integrated color management that adjusts printed colors to accurately match medical image monitors or user specified color profiles. The hardcopy output includes, however is not limited to, nuclear medicine, ultrasound, CT (especially 3-D reconstruction), MRI and Radiation Therapy planning. Images are suitable for medical image diagnosis use and referral. Digital images can be acquired from, but not limited to local area networks (LAN), Internet, medical image storage devices, or directly from digital medical image capture modalities.

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

Performance Data:

Safety and effectiveness are assured via meeting voluntary standards, including: DICOM, SMPTE, UL 60950, IEC 60601-1-1, 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 Color Medical Imager 1000 and predicate device, the Codonics EP-1000 Medical Color dry imager (K030690) have been designed to the equivalent safety standards.

Eastman Kodak therefore concludes that the KODAK Color Medical Imager 1000 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

SEP 2 4 2004

Mr. Stephen Slavens
Regulatory Affairs Director
Eastman Kodak Company
Health Imaging Group, Digital Output SPG
1 Imation Wav. 304-3B-61
OAKDALE MN 55128-3414

Re: K042159
Trade/Device Name: KODAK Color Medical Imager 1000
Regulation Number: 21 CFR 892.2040
Regulation Name: Medical image hardcopy device
Regulatory Class: II
Product Code: 90 LMC
Dated: August 5, 2004
Received: August 10, 2004

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): _____

Device Name: KODAK Color Medical Imager 1000

Indications for Use:

The Kodak Color Medical Imager 1000 series medical printers are thermal print engines intended to produce continuous tone photographic quality hard copy output with integrated color management that adjusts printed colors to accurately match medical image monitors or user specified color profiles. The hardcopy output includes, however is not limited to, nuclear medicine, ultrasound, CT (especially 3-D reconstruction), MRI and Radiation Therapy planning. Images are suitable for medical image diagnosis use and referral. Digital images can be acquired from, but not limited to local area networks (LAN), Internet, medical image storage devices, or directly from digital medical image capture modalities. The system of printer and physical image is not a high-resolution device and is not intended for use with FFDM systems.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____

(Per 21 CFR 801.109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042159