K042158

SEP 2 4 2004

Section B1

510(k) Summary

August 5, 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
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Device:

Trade name:	KODAK Medical Imager 300
Common name:	Thermal Printer
Classification name:	Medical Image Hardcopy Device 21 CFR 892.2040

Predicate device: Kodak DRYVIEW 8100 (K972163)

Intended Use of Device

The KODAK Medical Imager 300 Imager is intended use as a hard copy device for output from digital imaging source modalities for use in medical imaging diagnosis and referral. Electronic image information signals are managed in the Medical Imager 300 and transformed thermally to develop Eastman Kodak imaging media. The system of printer and physical image is intended for use with a variety of modalities, including, but not limited to CR, DR, CT, MRI, Ultrasound, Nuclear Medicine, etc. for diagnostic use by medical radiologists and communications to referring physicians and their patients.

Technological Characteristics:

The subject device and predicate devices use similar technology to create diagnostic films. The imagers receive image data from the modality. User control is performed directly by the modality or through the host control. KODAK imaging media is removed from a cartridge and transported to the imaging station. Image data addresses the individual pixel elements in the thermal print head. The heat of the thermal head reacts the thermally sensitive film to produce the image and the film 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 2601-1, IEC 60601-1, ISO 12207 and ISO 14971.

Conclusion:

The devices use different means to conform with electrical safety, but present any different safety issues. 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 Medical Imager 300 and predicate device KODAK DRYVIEW 8100 Laser Imager 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.

Eastman Kodak therefore concludes that the KODAK Medical Imager 300 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: K042158
Trade/Device Name: KODAK Medical Imager 300 Thermal Printer
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): K042158

Device Name: KODAK Medical Imager 300 Thermal Printer

Indications for Use:

The KODAK Medical Imager 300 Imager is intended use as a hard copy device for output from digital imaging source modalities for use in medical imaging diagnosis and referral. Electronic image information signals are managed in the Medical Imager 300 and transformed thermally to develop Eastman Kodak imaging media. The system of printer and physical image is intended for use with a variety of modalities, including, but not limited to CR, DR, CT, MRI, Ultrasound, Nuclear Medicine, etc. for diagnostic use by medical radiologists and communications to referring physicians and their patients. 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 R. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042158