K983905

JAN 25 1999

Appendix G -- Summary of Safety and Effectiveness

I. Date Prepared

October 30, 1998

II. Submitter

Eastman Kodak Company
Health Imaging Division
343 State Street
Rochester, New York 14650

III. Contact Person

Judith A. Wallace
Regulatory Affairs
(716) 724-2314

IV. Device Names

Trade Names:
KODAK DIGITAL SCIENCE 3600 Distributed Medical Imager
KODAK DIGITAL SCIENCE 1200 Distributed Medical Imager

Common Names:
3600 DMI; 3600 Imager
1200 DMI; 1200 Imager

V. Device Classification

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

VI. Predicate Device

KODAK EKTASCAN Medical Color Imager 2000PS ('KEMCI 2000'); 510(k) number K951948

VII. Description of Devices

KODAK DIGITAL SCIENCE 3600 Distributed Medical Imager is designed for mid to high end desktop Referral Imaging and Distributed Medical Imaging applications printing color or monochrome images on Medical Paper and/or Film Media up to 11x14 inch, with dual media supply trays and optional network interfacing.

KODAK DIGITAL SCIENCE 1200 Distributed Medical Imager is designed for low end to mid range desktop Referral Imaging and Distributed Medical

Imaging applications printing color or monochrome images on Medical paper and/or film up to 8.5x11 inch, with a single media supply tray.

Accessories: Media & Inks

- KODAK DIGITAL SCIENCE Distributed Medical Imaging Paper / 8.5x11 in.
- KODAK DIGITAL SCIENCE Distributed Medical Imaging Paper / A4
- KODAK DIGITAL SCIENCE Distributed Medical Imaging Paper / 4x6 in.
- KODAK DIGITAL SCIENCE Distributed Medical Imaging Film / 8x10 in.
- KODAK DIGITAL SCIENCE Distributed Medical Imaging Film / 11x14 in.
- KODAK DIGITAL SCIENCE Distributed Medical Imaging Cartridge / Black 1
- KODAK DIGITAL SCIENCE Distributed Medical Imaging Cartridge / Black 2
- KODAK DIGITAL SCIENCE Distributed Medical Imaging Cartridge / Color 1
- KODAK DIGITAL SCIENCE Distributed Medical Imaging Cartridge / Color 2

VIII. Indications for Use

KODAK DIGITAL SCIENCE Distributed Medical Imagers are computer peripheral printing devices used to make hard copy of medical images and reports on paper and/or film.

IX. Substantial Equivalence:

The purpose and functionality of the KODAK DIGITAL SCIENCE Distributed Medical Imagers is substantially equivalent to the KODAK EKTASCAN Medical Color Imager 2000PS. The basis for the equivalence is that the 3600 and 1200 Imagers, like the KEMCI 2000PS, are computer peripheral printing devices which print monochrome or color images on paper or transparency media. The primary difference is that the 3600 and 1200 Imagers directly deposit black or color inks onto the receiving media to render the image whereas the KEMCI 2000PS uses heat to transfer black or color dyes from a substrate material onto the receiving media.

Although technologically different, the function and output of the SE devices is similar to that of the predicate device and we conclude that the SE devices are as safe and effective as the predicate device.

Tabular Comparison of Features and Specifications of the Devices:

Specification	KODAK DIGITAL SCIENCE 3600 Distributed Medical Imager	KODAK DIGITAL SCIENCE 1200 Distributed Medical Imager	KODAK EKTASCAN Medical Color Imager 2000PS
Printing Method	Inkjet	Inkjet	Thermal Dye Sublimation
Interfaces	Parallel: IEEE 1284 Optional: Ethernet, 10Base2 RJ45	Parallel: IEEE 1284	Parallel: IEEE 1284 Optional: Ethernet, 10Base2 RJ45 SCSI (2 ports)
Standards	UL, CSA, FCC, EN50082, CISPR 22, VCCI, CE Mark, C-Tick, Energy Star, SETI Mark, SEMKO	UL, CSA, FCC, EN50082, CISPR 22, VCCI, CE Mark, C-Tick, Energy Star	UL, CSA, TUV-GS, FCC, ICES, EN500, VCCI, CE Mark
Sheet Sizes	A3 (11.69x16.54 in.) Tabloid (11x17 in.) 11x14 in. 8x10 in.	8x10 in. Letter Legal A4	8.5x11.0 in. 8.5x11.7 in. 8.5x14.0 in. 9.5x14.0 in.

	Letter Legal A4 Executive B5 A5 Custom: 3x5 in. min. 12.6x22 in. max.	Executive B5 A5 A6	
Print Media	Coated Paper Transparency (blue) Plain Paper Card Stock	Coated Paper Transparency (blue) Plain Paper Card Stock	Coated Paper Transparency (clear)
Media Supplies	1 or 2	1	1
Monochrome Printing	Yes	Yes	Yes
Color Printing	Yes	Yes	Yes
Print Resolution	1200 dots per inch	1200 dots per inch	300 pixels per inch
Hard Drive	optional	none	none
Memory	8-64 MB RAM	n/a	48 MB RAM

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 1999

Judith A. Wallace
Regulatory Affairs Associate
Eastman Kodak Company
Health Imaging Division
901 Elmgrove Road
Rochester, NY 14653

Re: K983905
Kodak Digital Science 1200 & 3600 Distributed Medical Imagers
Dated: October 30, 1998
Received: November 3, 1998
Regulatory class: II
21 CFR 892.2040/Procode: 90 LMC

Dear Ms. Wallace:

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 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). 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,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Facsimile of CDRH's "Indication for Use" Page

510(k) Number (if known): K983905

Device Name:

KODAK DIGITAL SCIENCE 3600 Distributed Medical Imager
KODAK DIGITAL SCIENCE 1200 Distributed Medical Imager

Indication of Use:

KODAK DIGITAL SCIENCE Distributed Medical Imagers are computer peripheral printing devices used to make hard copy of medical images and reports on paper and/or film.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K983905

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The-Counter ____
(Per 21 CFR 801.109)