# SUMMARY OF SAFETY AND EFFECTIVENESS

## I. INTRODUCTION

OCT - 7 1997

The Kodak Digital Science 9000D Medical Laser Printer (MLP 9000D) is a secondary imaging device that receives data from various modalities that can be stored and then printed on film for evaluation by a radiologist. The MLP 9000D is an integrated system which is based on the overall system concept of the Kodak Ektascan 2180 Laser Printer (KELP 2180), Common Protocol (CP) interfaces and the Kodak X-Omat 180LP/LPS Processor system. The MLP 9000D's film transport and exposure mechanisms will be a modification of the current KELP 2180 design. The Kodak X-Omat 180LP/LPS will be replaced by a dry thermal processor that will be used to develop a new photothermographic film.

The MLP 9000D will consist of many components which are similar to the KELP 2180. Examples are various input sections that are either video, digital, digital video, or network interfaces that interact between the host and the MLP 9000D to perform its tasks. The operator interfaces with the system by either using a keypad to store and print images or with an autofilming link to perform the same storing and printing functions at a system console.

## II. GENERAL INFORMATION

Name of Manufacturer:
Eastman Kodak Company
Health Imaging Division
901 Elmgrove Road
Rochester, New York 14653-5513

Establishment Registration Number:
1317307

Device Name:
KODAK Digital Science 9000D Medical Laser Printer

Device Classification:
Class II Device

III. THE DEVICE

The general hardware configuration of the KODAK Digital Science 9000D Medical Laser Printer contains the following major components / subsystems:

Modality Interfaces
Laser Printing System
Processor with optional Film Sorter

OPTIONAL ACCESSORIES:

Image Buffer Controller / for KODAK DIGITAL SCIENCE 9000D Medical Laser Printer and KODAK EKTASCAN 2180 Laser Printer

High Capacity Image Buffer Disk / for KODAK DIGITAL SCIENCE 9000D Medical Laser Printer and KODAK EKTASCAN 2180 Laser Printer

Memory Board / 6 MP / for KODAK DIGITAL SCIENCE 9000D Medical Laser Printer and KODAK EKTASCAN 2180 Laser Printer

Seismic Kit / for KODAK DIGITAL SCIENCE 9000D Medical Laser Printer and KODAK EKTASCAN 2180 Laser Printer

Standard Image Buffer / for KODAK DIGITAL SCIENCE 9000D Medical Laser Printer and KODAK EKTASCAN 2180 Laser Printer

Basic Image Buffer / for KODAK DIGITAL SCIENCE 9000D Medical Laser Printer and KODAK EKTASCAN 2180 Laser Printer

Enhanced Image Buffer / for KODAK DIGITAL SCIENCE 9000D Medical Laser Printer and KODAK EKTASCAN 2180 Laser Printer

High Capacity Enhanced Image Buffer / for KODAK DIGITAL SCIENCE 9000D Medical Laser Printer and KODAK EKTASCAN 2180 Laser Printer

IV. INDICATION FOR USE

Images printed on film from the Laser Printer will be used for primary diagnoses, similar to other laser printers and CRT multi-format cameras. Evaluation of the hard copy output by trained health care professionals provides adequate opportunity for competent human intervention. Laser printers are not represented to be of use in supporting or sustaining human life, nor do they present a potential for unreasonable risk of illness or injury.

V. COMPARISON OF FEATURES

| IMAGING FEATURES | KELP 2180 | 9000 D | DV 8700 |
|---|---|---|---|
| Laser Type | Red Diode | Red Diode | IR-Diode |
| Deflection | Polygon | Polygon | Galvo |
| xxxxScan | Scan Roller | Scan Roller | Galvo |
| Image Matrix | 4096x5120 | 4096x5120 | 4096x5120 |
| Bits/Pixel | 12/12 | 12/12 | 12/12 |
| Trim Option | Yes | Yes | Yes |
| Pixel Pitch (Microns) | 79 | 79 | 80 |
| Laser Power | 5mw | 50mw | |
| **TONE SCALE FEATURES** | | | |
| Contrast | -5 to +5 | -5 to +5 | |
| Density Max | 3.2 | 3.2 | |
| Curve Shape | 6 | 6 | |
| Interpolation | Cubic/Rep/ Sharp Cubic/Bilinear | Cubic/Rep Sharp Cubic/Bilinear | Cubic/Rep |
| **PHYSICAL FEATURES** | | | |
| Footprint (in.) | 31 x 52 | 31 x 52 | 32 x 26 |
| Kodak Processor | 180LP Wet | Thermal | Thermal |
| Roomlight Film Supply | Yes | Yes | Yes |
| Film Sizes | 4 | 4 | 1 |
| **PRODUCTIVITY** | | | |
| Lockout Time (sec) | 0 | 0 | 0 |
| Cycle Time (sec) | 20 | 30 | 30 |
| Print Time | 12 | 26 | |
| Memory Capacity (MB) | 4G | 4G | 128MB |
| Autoprint | Yes | Yes | Yes |
| Random Erase | Yes | Yes | Yes |
| **MULTIPLE INPUTS** | **KELP 2180** | **9000 D** | **DV 8700** |
| Max Inputs | 8 | 8 | 8 |
| Volatile Memory | No | No | Yes |
| Keypad/Autofilm | Yes | Yes | Yes |

## VI. REGULATORY COMPLIANCE

The Kodak Digital Science 9000D Medical Laser Printer (MLP 9000D) is being designed and tested in conformance with the following standards.

### Product Safety

| | |
|---|---|
| EN 60601-1 | Medical Electrical Equipment, General Requirements |
| EN 60825 | Safety of Laser Products, Part 1: Equipment Classification, Requirement, and User's Guide |
| CSA C22.2 No. 601.1 | Medical Electrical Equipment, Part 1: General Requirements |
| UL 2601-1 | Medical Electrical Equipment, General Requirements |
| Laser safety: | Title 21CFR CHAPTER 1, /subchapter J, Part 1040.10 |

### Electromagnetic Interference

EN 55011 Class B/1992, EN 50082-1/1992, EN 60950/1993
following the provisions of the applicable directives
89/336/EEC and amendments
72/23/EEC and amendments

EN 61000-3-2 Power Line Harmonics

EN 61000-3-3 Flicker

### Electromagnetic Noise Susceptibility

EN 50082-1:92, Generic Immunity
as tested per the following:

(a) IEC 801-2:91; ESD, 4 KV direct, 8 KV air.
(b) IEC 801-3:84; RF Immunity Severity Level 2.
(c) IEC 801-4:88; EFT Severity Level 2

### Seismic

Requirements of the State of California, Office of Statewide Health Planning and Development for "Pre-Approval" in accordance with California Administrative Code, Title 24, Part 2 and Title 22, Division 7, Chapter 7.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 7 1997

Robert L. Hiller
Director, HI Regulatory Compliance
Eastman Kodak Company
Health Imaging Division
901 Elmgrove Road
Rochester, NY 14653

Re: K972847
Kodak Digital Science 9000D Medical Laser Printer
Dated: July 30, 1997
Received: August 1, 1997
Regulatory class: Unclassified
Procode: 90 LMC

Dear Mr. Hiller:

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 requirement, 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/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): K972847

Device Name: KODAK DIGITAL SCIENCE 9000D MEDICAL LASER PRINTER

INDICATION FOR USE:

The KODAK Digital Science 9000D Medical Laser Printer is a laser printer designed to produce hard-copy films of digitized medical images. It is a newly designed printer to be added to Kodak's family of medical laser printer products that is intended for the centralized network printing solution for high volume sites for maximum productivity. This printer will be environmentally friendly by eliminating wet chemistry, site concerns, costs and will reduce chemical disposal problems. This is accomplished by using a totally proprietary imaging process.

Images printed on film from the laser printer will be used for primary diagnosis, similar to other laser printers and CRT mult-format cameras. Evaluation of the hard copy output by trained health care professionals provides adequate opportunity for competent human intervention. Laser printers are not represented to be of use in supporting or sustaining human life, nor do they present a potential for unreasonable risk of illness or injury.

Sincerely yours,

Robert L. Hiller 7/20/97

Robert L. Hiller
Director, Regulatory Affairs
KODAK Health Imaging

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-the-Counter Use ✓
(per 21 CRF 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972847