

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**I. Date Prepared:**

September 12, 1997

II. Submitter:

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

III. Contact Person:

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

IV. Device Name:

Trade Name Kodak Digital Science Dental Image Viewer

Common Name Dental x-ray image enhancement system

V. Device Classification:

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

VI. Predicate Device:

TAU Corporation TigerScan/TigerView -- 510(k) No. K955237

VII. Description of Device:

The KODAK DIGITAL SCIENCE™ Dental Image Viewer is a software package designed to provide full resolution digitized images of a dental x-ray film for diagnostic review, insurance adjudication and patient consultation. The KODAK DIGITAL SCIENCE™ Dental Image Viewer is designed to operate on a standard PC-compatible computer.

KODAK DIGITAL SCIENCE™ Dental Image Viewer features the display of full-mouth sets and other mounts, high-resolution image display and manipulation, and interfaces with practice management systems.

VIII. Indications for Use:

Intended uses in the dental industry include the following:

- Radiograph viewing and manipulation for insurance claims adjudication.
- Radiograph viewing and manipulation for diagnostic purposes
- Radiograph viewing for patient education and consultation.

When used for diagnostic purposes, the patient population will be the general public, and the diseases/conditions that the device will be used to diagnose are; dental caries, periodontal disease and bone loss, tooth fractures, jaw misalignment, and other diseases and conditions that are encountered by general practitioners and specialists in the dental care field.

IX. Substantial Equivalence:

The purpose and functionality of the KODAK DIGITAL SCIENCE™ Dental Image Viewer is substantially similar to the TAU Corporation TigerView system (K955237), as well as numerous other x-ray viewers currently on the market. The basis for the equivalence is that both systems consist of software which will enhance images for diagnosis. The following table summarizes the two products functional equivalence

Description	Kodak Dental Image Viewer	TAU TigerView
Host Platform:	Pentium Processor based Personal Computer	IBM - Compatible Computer
Operating System:	Windows 95	Windows 3.1. Windows for Workgroups 3.11 or Window 95
Host RAM:	32 MB	16 MB
Host Magnetic Storage:	10 MB	at least 400 MB
Host Floppy Drives:	3.5 inches	3.5 inches
Host Processor Speed:	Any Pentium speed	486 66Mhz or better CPU
Host Monitor Size:	15" diagonal minimum	
Display resolution	800 X 600 at 24 bit color minimum	800 X 600
Open Case Preview:	No	Yes
User Display Preferences:	Yes	No
Receive Images from other Systems:	Yes	Yes

Description	Kodak Dental Image Viewer	TAU TigerView
Patient List Transmission Status:	No	Receiving status is displayed.
Image Manipulation:	Rotate, Zoom, Flip, Contrast, Brightness	Rotate, Zoom, Flip, Contrast, Brightness, Negative Image
Monitor Calibration:	Yes	



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 10 1997

Judith A. Wallace
Regulatory Affairs Associate
Eastman Kodak Company
Health Imaging Division, Dental Business
343 State Street
Rochester, NY 14650-1122

Re: K973476
Kodak Digital Science - Dental Image Viewer
Dated: September 12, 1997
Received: September 15, 1997
Regulatory class: II
21 CFR 872.1800/Procode: 90 EHD

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 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

FACSIMILE OF CDRH'S "INDICATIONS FOR USE" PAGE

510(K) Number (if known):

Device Name: KODAK DIGITAL SCIENCE - Dental Image Viewer

Indication of use: Viewing of dental radiographic film

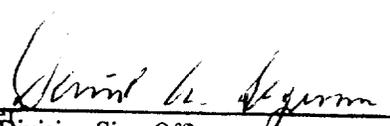
Concurrence of CDRH, Office of Device Evaluation

Prescription Use
 (Per 21 CFR 801.109)

OR

Over-The-Counter

KODAK DIGITAL SCIENCE - Dental Image Viewer
510(k) Submission


(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

9/12/97

510(k) Number

K973476

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