## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS K971894

AUG 20 1997

### I. Date Prepared:

April 13, 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 Scanning System

Common Name Dental x-ray scanning and image enhancement system

## V. Device Classification:

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

## VI. Predicate Device:

Kodak Digital Science Film Digitizer L7501/L7506 -- 510(k) No. K961768
TAU Corporation TigerScan/TigerView -- 510(k) No. K955237

## VII. Description of Device:

The KODAK DIGITAL SCIENCE™ Dental Scanning System consists of the KODAK Image Magic ™ Print Scanner 2000, a transparency adapter, and TWAIN Data Source software. The KODAK Image Magic™ Print Scanner 2000 is a 36 bit 600 dpi flatbed scanner connected to the user's computer through a SCSI interface. The transparency adapter provides an overhead light source for transparent media. The TWAIN Data Source software is used to control the scanner, optimize the scanned image using tone scaling algorithms, and communicate with application software through the TWAIN interface.

Kodak's Dental X-ray Scanner (KODAK DIGITAL SCIENCE™ Dental Scanning System or KDS DSS) is designed to support; dental radiography scanning to convert film

to digital form. The KDS DSS is designed to operate on a standard PC-compatible computer and accomplish scanning with a commercially available quality flatbed scanner interfaced to the PC.

The KDS Dental Scanning System is a fully functional digital radiograph scanning system. Features include; advanced graphical user interface, intelligent scanning and image enhancement, scanning of full-mouth sets and other mounts, and interfaces to practice management systems.

## VIII. Indications for Use:

The KODAK DIGITAL SCIENCE Dental Scanning System is designed to interface with practice management software. The system allows for much quicker consultations with experts in distant facilities. Also, archiving electronically for faster image recall and assembly of historical studies can be accomplished with ease. The KODAK DIGITAL SCIENCE Dental Scanning System is designed to interface with practice management software.

Intended uses in the dental industry include the following:

- Scanning of film

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 Scanning System is substantially similar to the TAU Corporation TigerScan/TigerView system (K955237), the KODAK DIGITAL SCIENCE Film Digitizer L7501/L7506 (K961768) as well as numerous other x-ray digitizers currently on the market. The basis for the equivalence is that both systems consist of a flatbed scanning device interfacing with a personal computer which digitizes dental x-ray film with image preview software containing similar functionality. The following table summarizes the three products functional equivalence.

**Product Functional Equivalence Comparison**

| Function | KODAK DIGITAL SCIENCE Dental Scanning System | KODAK DIGITAL SCIENCE Film Digitizer | TAU TigerScan/TigerView |
|---|---|---|---|
| Conversion of film to digital image | **Commercial Flatbed Scanner with TPU** | Commercial Flatbed Scanner with TPU | Commercial Flatbed Scanner with TPU |
| Control of scanner, storage, retrieval, transmission, and receipt of digital images | **Personal Computer** | Personal Computer | Personal Computer |
| Mouse, windows, menus, etc. Used to control device | **Graphical User Interface (GUI)** | Graphical User Interface (GUI) | Graphical User Interface (GUI) |
| Image display and optimization | **Image Processing** | Image Processing | Image Processing |
| Integrate with practice management systems | **TWAIN Interface** | TWAIN Interface | Proprietary API |
| | | | |

Each system performs high definition scanning of images from dental x-ray film for display on monitors. Based on input quality the level of clarity and definition is similar, although the KODAK DIGITAL SCIENCE Dental Scanning System has the ability with its proprietary enhancement algorithms to image enhance.

The only real difference in the systems is the choice of hardware, interface connection options and the ability to enhance poor quality images. Both systems use reliable, mature components. The software and system functionalities are comparable with few minor exceptions in image enhancement ( refer to image quality/enhancement test results).

Based on the similarities of the purpose and functionalities of these three systems, Kodak concludes that the KODAK DIGITAL SCIENCE Dental Scanning System is substantially equivalent to the TAU Corporation TigerScan/TigerView x-ray scanning and imaging device and the KODAK DIGITAL SCIENCE Film Digitizer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 20 1997

Judith A. Wallace
Regulatory Affairs Associate
Eastman Kodak Company
901 Elmgrove Road
Rochester, NY 14653-5517

Re: K971894
Kodak Digital Science - Dental Scanning System
Dated: May 16, 1997
Received: May 22, 1997
Regulatory class: Unclassified
Procode: 90 LMA

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): K971894

Device Name: KODAK DIGITAL SCIENCE - Dental Scanning System

Indication of use: Scanning of dental radiographic film

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Concurrence of CDRH, Office of Device Evaluation

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

David A. Seguson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971894 5/16/97