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K961768

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

I. DATE PREPARED: May 3, 1996

II. SUBMITTER:

Eastman Kodak Company
Health Imaging Division
18325 Waterview Parkway
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III. CONTACT PERSON:

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IV DEVICE NAME:

Trade Name	KODAK Digital Science Film Digitizer L7501 KODAK Digital Science Film Digitizer L7506 (with Film Autofeeder)
Common Name	Picture Archiving and Communications Systems (PACS) Components

V DEVICE CLASSIFICATION

FDA has classified the predicate device as Regulatory Class II under 21 CFR 892.1750.

VI. PREDICATE DEVICE:

KODAK Film Digitizer ("FD")

VII. DESCRIPTION OF DEVICE:

Kodak's Film Digitizer (KODAK DIGITAL SCIENCE Film Digitizer or KDS FD) is a system designed to convert X-ray films into digital images for display, transmission, and/or archiving. The KDS FD is designed to accomplish its interface over the American College of Radiology-National Electrical Manufacturers Association (ACR-NEMA) standard known as DICOM (Digital Imaging and Communications in Medicine) which gives direct access to imaging devices, Local Area Networks (LANs), and Wide Area Networks (WANs).

VIII. INDICATIONS FOR USE:

The KDS FD is designed to allow operators and physicians greater access to images by transmitting them electronically over networks instead of physically sending films. 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 KDS FD is a DICOM conformant digitization product designed for use within a Picture Archiving and Communication System (PACS).

IX. Substantial Equivalence

The purpose and functionality of the KDS FD is substantially similar to the Vortech (Kodak) FD system (K915362, November 27, 1991), as well as numerous other x-ray digitizers currently on the market. The basis for the equivalence is that both systems consist of a Lumisys laser film digitizer with image preview software with similar functionality.

Each system performs high definition scanning of images on film for display on monitors. The level of clarity and definition is similar. The ability to input and tie in patient information to complete records is similar -- the FD allowed for manual data entry **only** whereas the KDS FD allows for manual data entry **or** an interface into a HIS/RIS to capture patient demographic data.

The transmission of the images across networks is also supported by both systems. Kodak used ACR-NEMA 2.0 for the FD and will use DICOM for the KDS FD. The function of image routing is supported by both systems.

The only real difference in the systems is the choice of hardware. Both systems use reliable, mature components. The software and system functionalities are comparable with few minor exceptions in patient information fields and networking options.

Based on the similarity of the purpose and functionalities of these two systems, Kodak concludes that the KODAK DIGITAL SCIENCE Film Digitizer is substantially equivalent to the Kodak Film Digitizer.