

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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I. **DATE PREPARED:** March 4, 1996

II. **SUBMITTER:**

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IV. **DEVICE NAME:**

Trade Name - KODAK DIGITAL SCIENCE (KDS) Medical Image and
Information Library (MIL)
Common Name - Image Storage, Distribution, and Library

V. **DEVICE CLASSIFICATION**

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

VI. **PREDICATE DEVICE**

Vortech (Kodak) Image Archive and Retrieval System--K915094

VII. DESCRIPTION OF DEVICE

The system consists of three main components: 1) the host CPU (a Sun SPARCstation 5 or 20) with pre-installed proprietary software, 2) the magnetic cache (a Sun SPARC storage Array RAID subsystem), and 3) a KODAK DIGITAL SCIENCE ADL 150 writeable CD jukebox. The RAID subsystem and the CD jukebox are managed by a hierarchical storage library that presents these two subsystems to the system software running on the host CPU as a single, very large filesystem. The power supply Provides power to operate the unit from a line voltage for 100, 120, 220, or 240 VAC, 50/60 Hz.

VIII. INDICATIONS FOR USE

The KODAK DIGITAL SCIENCE (KDS) Medical Image and Information Library is a DICOM conformant archival product designed for use within a Picture Archiving and Communication System (PACS). The system utilizes a prefetching algorithm to facilitate fast access to previous imagery.

V. COMPARISON OF FEATURES

SIDE-BY-SIDE COMPARISON TABLE

K-number	This 510(k)	K915094
Range of Storage	8GB to 216GB	37GB to 1.4TB
Type of Interface	SCSI	SCSI
Type of Media	5.25" CD-Recordable	12" WORM Platters
DICOM Conformant	Yes, Native	No
HIS/RIS Interface	Yes	No
Host Platform	Sun	Sun
Jukebox, Maximum	Yes, 150-CD	Yes, 140-Platters
Compression	Yes, lossless 2:1	Yes, lossless 2:1
Database Structure	Distributed	Distributed