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JAN 20 1998

510(k) SUMMARY of Safety and Effectiveness

1.1 Company Identification

Mitra Imaging, Inc.
115 Randall Drive
Waterloo, Ontario, Canada
N2V IC5
Tel: (519) 746-2900
Fax: (519) 746-3745

1.2 Official Correspondent

Gary J. Allsebrook
Regulatory Management Services
16303 Panoramic Way
San Leandro, CA, USA, 94578-1116

1.3 Date of Submission

October 31, 1997

1.4 Device Name

Classification Name:	PACS
Common/Usual Name:	Image Archive System/ Teleradiology System
Proprietary Name:	Image Vault

1.5 Substantial Equivalence

The Image Vault software is substantially equivalent to the Kodak Cardiology Digital Archive & Review System (Cardiac Archive Station, CAS 6000), K960043.

1.6 Device Description and Intended Use

Image Vault is a software package which may be marketed as a software only solution, as well as in conjunction with standard PC hardware. Image Vault is a PC-based, DICOM-compliant PACS device that is able to send & receive, display, store, and archive DICOM non-compressed and JPEG-compressed images. Images can be archived using standard magnetic tapes. It also has the ability to read/write a collection of images to/from CD-R media in a method defined by DICOM.

Images can be viewed using a simple display utility, for the purposes of properly identifying patients and their corresponding studies, and is not intended to be used for diagnosis.

Image Vault uses standard "off-the-shelf" PC hardware and communicates using the standard TCP/IP stack. The network hardware used to support the TCP/IP stack is superfluous to Image Vault.

1.7 Software Development

Mitra certifies that the Image Vault software is designed, developed, tested and validated according to written procedures. These procedures identify individuals within the organization responsible for developing and approving product specifications, coding and testing, validation testing and field maintenance. The software used in this product is used for cardiology and storage only and does not affect image quality.

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1.8 Substantial Equivalence Comparison Chart

Substantial Equivalence Comparison Chart (Image Vault)

Specification	Image Vault	Kodak Cardiac Archive Station CAS 6000
Graphical User Interface	Yes	Yes
Patient Demographics	Yes	Yes
Display Resolution	1024x768	1024x768
Communications	TCP/IP	TCP/IP
Image Review	Flip/Rotate/Pan/Zoom/Sequential	Flip/Rotate/Pan/Zoom/Sequential
CD Writers Supported	Yamaha CDR400 Yamaha CDR100	Kodak PCD Writer 600
CD Labeling	Yes	Yes
Temporary Image Storage	Yes	Yes
Image Archiving (Hard Disk)	Yes	Yes
Image Archiving (Magnetic Tape)	Yes	No
Magnetic Tape Drives Supported:	ADIC Scalar 218 ADIC Scalar 448	No
Platform	PC	PC
JPEG	Yes	Yes

1.9 Safety and Effectiveness

In accordance with the provisions of the Safe Medical Device Act of 1990, Mitra Imaging, Inc. is providing a summary of safety and effectiveness information regarding the Image Vault software.

General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and indication for use.

The hardware components specified (but not supplied) are all "off the shelf" computer components.

Validation and Effectiveness:

Extensive testing of the software package has been performed by programmers, by non-programmers, and by potential customers. Software is only used for control purposes and has no bearing on image quality. There is no image processing used with this software.

Images that are compressed are properly identified in the image information as being compressed as specified by the DICOM standard. This compression identification remains with the image for the entire life of the image.

Substantial Equivalence:

The Image Vault software is a software package used for archiving cardiac images and for writing to CD-ROM media. The intended use and technological characteristics of the system are similar to the Kodak Cardiac Archive Station CAS 6000. Any differences between the Image Vault software and the equivalent device have no significant influence on safety or effectiveness.

Its is our conclusion that there is no software component that we know of in the Image Vault software whose failure or latent design flaw would be expected to result in death or injury to a patient.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 20 1998

Mitra Imaging, Inc.
c/o Gary J. Allesbrook
Regulatory Management Services
16303 Panoramic Way
San Leandro, CA 94578-1116

Re: K974102
Image Vault
Dated: October 31, 1997
Received: October 31, 1997
Regulatory class: Unclassified
Procode: 90 LMD

Dear Mr. Allesbrook:

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,

William Yin

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): K974102

Device Name: Image Vault

Indications for Use:

Vault is intended to act as a long term storage device (archive) for medical images.

Vault is a networked device that acts as a DICOM Storage Service Class Provider (SCP):

- Images can be sent to it via the DICOM protocol, from modalities or other devices that are sources of medical images.
- Images can subsequently be queried and retrieved via the DICOM protocol, to imaging workstations and other processing devices.
- Internally, Vault is optimized to provide secure storage for a very large number of images, and to provide rapid retrieval on demand. To that end, Vault includes high capacity storage media, and has implemented hierarchical storage management software to manage cache storage effectively.

Users:

The Vault will be located in a hospital department. The expected users are as follows:

Service personnel for installation, configuration and support.

- System administrator within the department, who in many cases will be chief technologist or other designated clinical staff.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use ____
(Per 21 CFR 901.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974102