

510(k) SUMMARY

1.1 Company Identification

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1.2 Official Correspondent

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1.3 Date of Submission

February 21, 1997

1.4 Device Name

Classification Name:	PACS
Common/Usual Name:	Teleradiology System
Proprietary Name:	Film Express

1.5 Substantial Equivalence

The Film Express software is substantially equivalent to the Lumisys DICOM TOOLKIT, Imageshare 910, or Statview.

1.6 Device Description and Intended Use

The intended user of this device is a DICOM software package that will enable any hospital PC with adequate monitor and enough memory to be used as a radiographic image viewer. It is designed to be utilized with Radiological Quality scanners, such as the Lumisys, Lumiscan film digitizers, and other DICOM conformant devices such as CT scanners or clinical workstations.

1.7 Software Development

Mitra certifies that the Film Express 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 teleradiology and/or storage only and does not affect image quality.

1.8 Substantial Equivalence Comparison Chart

Substantial Equivalence Comparison Chart (Film Express)

Specification	Film Express	DICOM Toolkit	Imageshare/FD (910)	Statview/DX
Graphical User Interface	Yes	Yes	No	Yes
Scanners Supported	Radiological Quality scanners, such as Lumisys 20/50/75/85/100/150/200	50, 75, 150, 200	50, 75, 100, 150, 200	50, 75, 100
Patient Demographics	Yes	Yes	Yes	Yes
Display Resolution	1024x768	1024x768	N/A	800x600, 1024x768, 1280x1024, 1200x1600
Communications	TCP/IP	TCP/IP	TCP/IP	TCP/IP
Image Review	Flip/Rotate/Pan/Zoom	Flip/Rotate/Pan/Zoom	Flip/Rotate	Flip/Rotate/Pan/Zoom
Temporary Image Storage	Yes	Yes	Yes	Yes
Platform	PC	PC	PC	PC
JPEG	Yes	No	Yes	No
DICOM Basic Printing	Yes	No	No	No

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 Film Express 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 Film Express software is a software package used for archiving and transmission of radiological images. The intended use and technological characteristics of the system are similar to the DeJarnette, Imageshare 910 Film Digitizing Acquisition Station. Any differences between the Film Express software and the equivalent device have no significant influence on safety or effectiveness.

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