

510(k) SUMMARY

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 Exhibit software.

1.1 Company Identification

Mitra Imaging, Inc.
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Waterloo, Ontario, Canada
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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

August 6, 1998

1.4 Device Name

Classification Name:	PACS
Common/Usual Name:	Teleradiology System
Proprietary Name:	Exhibit

1.5 Substantial Equivalence

The Exhibit software is substantially equivalent to the Algotec Systems Ltd. Product, MediSurf that is covered under K971347.

1.6 Device Description and Intended Use

Exhibit is a software package, which may be marketed as a software only solution, as well as in conjunction with standard PC hardware. Exhibit is a PC-based, DICOM-compliant PACS device that is able to receive and display DICOM images. Images sent to Exhibit are converted into formats suitable for viewing in a web browser, and stored in a local cache (hard disk). The algorithms used by Exhibit to create JPEG and wavelet images follow known and accepted protocols.

Images sent to Exhibit can be viewed using a Java applet that runs within a web browser such as Netscape or Internet Explorer. The Exhibit applet can be used for the purposes of viewing images over a hospital intranet, or over the internet from a remote location. Images stored on Exhibit are transient, as Exhibit is not intended to be an archiving device.

Exhibit 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 Exhibit.

1.7 Software Development

Mitra certifies that the Exhibit 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 to convert DICOM images to formats that can be displayed within web browsers.

1.8 Safety and Effectiveness

General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and indications 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, quality control staff, and by potential customers.

Substantial Equivalence:

The Exhibit software is a software package used to receive DICOM images, convert them to a web-browser compatible format, and to transfer those converted images to a viewing applet.

Exhibit is substantially equivalent to the Algotec MediSurf product, in that it receives DICOM images, converts them to wavelet format and displays them within a web browser. The intended use and technological characteristics of the system are virtually identical to MediSurf (K971347). Any differences between the Exhibit software and the equivalent device have no significant influence on safety or effectiveness.

It is our conclusion that there is no software component in the Exhibit product or hardware component which would be used in conjunction with the Exhibit product that we know of whose failure or latent design flaw would be expected to result in death or injury to a patient. Thus the "Level of Concern" of the Mitra Exhibit product is "minor".

1.9 Substantial Equivalence Chart

Specification	Exhibit (This submission)	MediSurf (K971347)
Graphical User Interface	Yes	Yes
Uses Java programming language	Yes	Yes
Applets viewed inside web browser	Yes	Yes
Applets stored on remote server	Yes	Yes
Communications	TCP/IP	TCP/IP
Image Review	Window Level/Flip/Rotate/Zoom	Window Level/Flip/Rotate/Zoom/Pan
Server Platform	PC – Windows NT	UNIX
Client Platform	Any Java-compatible web browser	Any Java-compatible web browser
JPEG for thumbnail view	Yes	No
Wavelet compression for transmission of images	Yes	Yes



NOV 3 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850MITRA Imaging, Inc.
c/o Gary J. Allesbrook
Regulatory Management Services
16303 Panoramic Way
San Leandro, CA 94578Re: K982769
Teleradiology System
Dated: August 6, 1998
Received: August 7, 1998
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

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 requirements, 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/dsma/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

510(k) Number (if known): K982769

Device Name: Mitra Imaging Inc., *Exhibit*

Indications For Use:

Exhibit is a software package, which may be marketed as a software only solution, as well as in conjunction with standard PC hardware. Exhibit is a PC-based, DICOM-compliant PACS device that is able to receive and display DICOM images. Images sent to Exhibit are converted into formats suitable for viewing in a web browser, and stored in a local cache (hard disk). The algorithms used by Exhibit to create JPEG and wavelet images follow known and accepted protocols.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 901.109)

(Optional Format 1-2-96)

David G. [Signature]
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982769