NOV - 8 2004

510(k) SUMMARY K042700

In accordance with the provisions of the Safe Medical Device Act of 1990, eRAD ImageMedical Corp., is providing a summary of safety and effectiveness information regarding the Image Medical Acquisition Station (IMAS), Picture Archiving and Communications System, digitized film acquisition software application.

1.1 Company Identification

ERAD/ ImageMedical Corp.
1132 W. Hamilton Street, Suite 312
Allentown, PA 18101
Establishment Registration: 2954766
Owner Operator Number: 9042966
Contact: Jim Connors, Vice President, Product Management
Tel: (864) 234-7430 ext. 106
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1.2 Official Correspondent

Gary J. Allsebrook
Regulatory Management Services
16303 Panoramic Way
San Leandro CA USA 94578-1116
Tel/fax: (510) 276-2648
Cell: (510) 388-5001
Email: regman10@comcast.net

1.3 Date of Submission

September 27, 2004

1.4 Device Name

Classification Name:	PACS
Common/Usual Name:	Soft-copy reading and acquisition system
Proprietary Name: (IMAS)	Image Medical Acquisition Station

1.5 Substantial Equivalence

Image Medical Acquisition Station (IMAS) software is substantially equivalent

to the to iCRco's Xscan32 (K002911) and Merge/eFilm's eFilm Scan (K020995

1.6 Device Description and Intended Use

IMAS is a software application used to acquire image data from film digitizers and send it to DICOM-compliant devices. IMAS executes on a Microsoft Windows NT, 2000 and XP workstation that is connected to a film digitizer via a SCSI cable. When IMAS initializes, it obtains some settings information from the film digitizer, and displays a user interface. From the user interface, a user logs onto IMAS using an account ID and password. Once logged into IMAS, the user has the ability to create patient and study information, instruct the film digitizer to scan one or more sheets of film and download the image data, group the data from one or more films into a folder, and send the resulting information to one or more configured destinations via DICOM.

When IMAS receives the image data from the film digitizer, it appears on the workstation monitor for review. At this point, the user can reorient the image by flipping and rotating it, adjust the window and level setting, or apply a zoom factor to it. If the digitized image is of a sheet of film containing multiple images, the user can separate the image into one or more images by defining the area of each image and creating a new image from the data in the selected area.

Lossy compressed mammography images and digitized film screen mammography images must not be reviewed for primary image interpretations. Mammography images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

1.7 Software Development

ERAD/ImageMedical Corp., certifies that the Image Medical Acquisition Station (IMAS) 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 developed for this product is used to provide diagnostic quality images and associated information to the indented users.

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:
IMAS has Indications for Use and a Target Population similar to other medical image devices, including iCRco's Xscan32 (K002911) and Merge/eFilm's eFilm Scan (K020995). All of the functions IMAS performs are available in at least one of the listed substantially equivalent devices. In most cases, the function is available in all of them. There are no significant differences between IMAS and the collective functions of all the predicate devices. See section E for additional information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 8 2004

ERAD Image Medical Corporation
% Mr. Gary J. Allsebrook
Official Correspondent
Regulatory Management Services
16303 Panoramic Way
SAN LEANDRO CA 94578-1116

Re: K042700
Trade/Device Name: Image Medical Acquisition Station (IMAS)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: September 27, 2004
Received: September 30, 2004

Dear Mr. Allesebrook:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

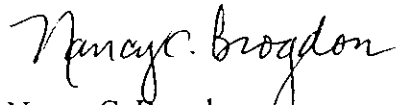
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K042700

Device Name: eRAD/ImageMedical Corp., **Image Medical Acquisition Station (IMAS),** Picture Archiving and Communications System

Indications For Use:

Image Medical Acquisition Station (IMAS) is a PACS and teleradiology software application used to acquire digitized film images, add and modify patient and study demographics, and transmit the results to DICOM PACS systems, archives and workstations. IMAS is for hospitals, imaging centers, radiologist reading practices and any user who requires and is granted access to patient image, demographic and report information.

Image Medical Acquisition Station (IMAS) is for use in hospitals, imaging centers, radiologist reading practices and any user who requires and is granted access to patient image, demographic and report information.

Lossy compressed mammography images and digitized film screen mammography images must not be reviewed for primary image interpretations. Mammography images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

(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)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042700