K994228
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FEB 22 2000

# Section 510(k)
# Premarket Notification

## Summary of Safety and Effectiveness Information

**Regulatory Authority:** Safe Medical Devices Act of 1990, 21 CFR 807.92

**Device Trade Name:** RemoteImage™ System

**Common Name:** Image Communication Device

**Regulation Number:** 892.2020

**Classification Name:** System, Image Processing

**Product Code:** LLZ

## Establishment Name & Registration Number:

**Name:** eTrauma, LLC
1425 East Newport Center Drive
Deerfield Beach, FL 33442
(954) 421-5623 (954) 570-6368 FAX

**Number:** To Be Applied For

## Classification:

**Device Class:** Class II

**Classification Panel:** Radiology

## Applicant / Contact Information:

eTrauma, LLC
Dan Hodgeman, President
1425 East Newport Center Drive
Deerfield Beach, Florida 33442
(954) 421-5623 (954) 570-6368 FAX

## Submission Correspondent:

Dan Hodgeman
eTrauma, LLC
1425 East Newport Center Drive
Deerfield Beach, Florida 33442
(954) 421-5623 (954) 570-6368 FAX

## Manufacturing Facility:

eTrauma, LLC
1425 East Newport Center Drive
Deerfield Beach, Florida 33442
(954) 421-5623 (954) 570-6368 FAX

## Equivalent / Predicate Devices:

**Autocyt Group, Inc.** K970064
AMICAS Web/Intranet Image Server

## Comparison to Predicate Device:

The RemoteImage™ system is substantially equivalent to the AMICAS Web/Intranet Image Server in that it is an integrated client-server software system designed to allow access to medical images by radiologists, referring physicians and other licensed professionals and is intended to allow the review of images using a personal computer or workstation configured for standard internet access. Like the AMICAS system, the RemoteImage system enables the client (medical professional) to access images through an Internet browser.

## Comparison Table:

| Feature | RemoteImage | AMICAS | S/E |
|---|---|---|---|
| **Indications for Use** | Similar | Similar | Yes |
| **Target Population** | Health Professionals | Health Professionals | Yes |
| **Uses Off-The-Shelf Hardware** | Yes | Yes | Yes |
| **Lossy[2]/Lossless Image Compression** | Yes/Yes | Yes/No | Yes |
| **TCP/IP Communications** | Yes | Yes | Yes |
| **Acquisition of Images** | DICOM Radiology Systems<br>Digital Film Scanner<br>Digital Camera<br>Other Imaging Modalities | DICOM Radiology Systems | Yes |

## Device Information:

**Description**

RemoteImage is a client-server software system designed to allow access to medical images by licensed medical professionals. This product is intended to allow the review of images from a modality of digital imaging systems (including the Vidar (k933632) film digitizer, a digital camera, a radiography system (PACS) or other modality) using a personal computer for standard Internet access. RemoteImage software is installed on a computer configured with connections to a mode of digital imaging and the internet. Once images are obtained,

[2] All lossy compressed images are labeled as such when viewed by end user.

the RemoteImage™ software converts the images from their original format to JPEG format and transmits them over 128 bit SSL encryption to an Internet server where they are stored for a specified period of time. Authorized medical personnel, upon password authentication, may download the images over 128 bit SSL encryption for viewing. The software program is written in C and is approximately 1 megabyte in size.

**Indicated Use**

The RemoteImage™ System is indicated to be used for remote viewing of medical image data.

**Level of Concern**

The severity of injury that the device could permit or inflict (directly or indirectly) on a patient or operator is minimal **(Lower Level of Concern)**. Failure of the device to function would result in the common practice of verbal telephone communications without the aid of visualization.

*Hazard Analysis*
Incorrect display of an image is possible due to incorrect data produced by the scanning modality or from a software malfunction. The method of control is through the current regulation of these devices by the FDA and/or through the testing procedures adhered to during development and testing stages of the device software prior to release. The corrective action is the intended use of this software with properly regulated devices, and timely identification and correction of these potential software problems and the subsequent testing procedures.

**Testing**

Testing of the RemoteImage software included transmitting 2,016 images in an aggregate for a seven day period. During each 24 hour period, three images were sent quarterly on the hour. All images during the testing phase were delivered successfully in complete and usable format with a loss of zero percent. During testing, a five percent retransmission rate was experienced using modem connectivity. These were successfully retransmitted within 120 seconds via the RemoteImage software reconnection functionality thereby reaching the 100 percent final delivery ratio above stated.

## Standards

**Performance:** None
**Voluntary:** ACR/NEMA DICOM

## Hardware/Software Information:

### Off-The-Shelf (OTS) Software

The RemoteImage system utilizes OTS hardware and software.

The end user does not directly interact with the OTS software, therefore, there are no end user decisional inputs required to the OTS software. No OTS software documentation will be provided to the end user.

The inherent graphics, automation, calculation and communications processing power in the OTS software is the optimal platform for accomplishing the system's goal of efficient delivery of image data via the Internet.

*Expected Limitation*

There are no expected design limitations of the OTS software as the use of the software is within the current limits of the OTS software intended use. Use of the OTS software does not extend beyond, or specifically modify in any way, the original specifications set by the OTS software manufacturer.

Since the RemoteImage server is central and not located at a user facility, the end user of the RemoteImage system will not be required to configure or manage any OTS software. The user will not directly interact with the OTS software, therefore, there are no end user decisional inputs required to the OTS software.

*Testing*

Testing of the OTS software included transmitting 2,016 images in an aggregate for a seven day period. During each 24 hour period, three images were sent quarterly on the hour. All images during the testing phase were delivered successfully in complete and usable format with a loss of zero percent. During testing, a five percent retransmission rate was experienced using modem connectivity. These were successfully retransmitted within 120 seconds via the RemoteImage software reconnection functionality thereby reaching the 100 percent final delivery ratio above.

*Tracking*

The end user does not directly interact with the OTS software. All OTS software is installed, manipulated, maintained, and stored on a central server by the Company's Informations System Administrator.

## Release Version Number

RemoteImage™ software current release version is 1.1.0

## Safety and Effectiveness Information

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**Factors Considered**

*The risk or danger to the patient as a result of using the system:*

The RemoteImage system cannot immediately threaten a patient's life nor directly cause irreversible illness or permanent injury as it deals only with image data and is intended to be viewed by a competent medical professional.

*Degree of influence on therapy or diagnosis:*
The RemoteImage system does not control the delivery or energy, administration or parenteral drugs, or life-sustaining functions. It does not provide a diagnosis. It provides information/data only. Competent health professionals would reasonably be expected to exercise judgement in the use of the information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 22 2000

Dan Hodgeman
President
eTrauma, LLC
1425 East Newport Center Drive
Deerfield Beach, FL 33442

Re: K994228
RemoteImage System
Dated: December 9, 1999
Received: December 15, 1999
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Hodgeman:

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 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). 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,

Capt. Daniel G. Schultz, M.D.
Acting 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:** Unknown K994228

**Device Name:** RemoteImage™ System

## Indications For Use:

The RemoteImage™ System is indicated to be used for remote viewing of medical image data.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguine

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K994228

Prescription Use ✓ OR Over-The-Counter Use _____

(Optional Format 1-2-96)