

**autocytgroup, inc.**

52 Marshall Street  
Watertown, MA 02172

800 490 8465  
617 926 4170 fax

MAR 17 1997

Document Mail Center (HFZ-401)  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD 20850

K970064

## 510(k) Summary

### 1. Identification

Date: January 6, 1997  
Submitter: Adrian Gropper, M.D.  
Autocyt Group, Inc.  
52 Marshall Street  
Watertown, MA 02172  
Contact: Adrian Gropper, M.D.  
617-925-5329  
617-926-4170 (fax)

FDA/CDRH/ODE/DMC

7 JAN 97 14 19

RECEIVED

### 2. Device Name

Trade Name: AMICAS Web/Intranet Image Server  
Common Name: Image Communication Device

### 3. Registration Number

None

### 4. Classification

Class: 2  
Panel: RA  
Product Code: SYSTEM, DIGITAL IMAGE COMMUNICATIONS

### 5. Standards

Performance: None established.  
Voluntary: ACR/NEMA DICOM 3.0

### 6. Labeling

See Section 3

## **7. Safety and Effectiveness Information**

AMICAS is an imaging software program used to view medical images on a personal computer. The software is designed to function with off the shelf hardware and software products including standard communications products. It does not require specialized, or nonstandard, devices of any type.

Image acquisition is via the industry-standard DICOM 3.0 protocol allowing the images to be produced from the digital data originated by the scanner. Image acquisition does not depend on the capture of video signals.

**The AMICAS software falls in the "Lower Level of Concern" category:**

**Intended Use:** The software is to be used for the remote viewing of files generated by a medical scanning device and acquired according to the dominant industry-standard communications format (DICOM 3.0).

**System and Software Requirements:** The software will run on standard off-the-shelf hardware and system configurations.

**Hazard Analysis:** Incorrect display of the image data is possible due to incorrect data produced by the scanner or from a software malfunction. The method of control is through the current regulation of these devices by the FDA, and through the testing procedures adhered to during development and testing stages of this 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.

**Factors Considered:**

**The risk or danger to the patient of using the device:** The software can not immediately threaten the patient's life nor directly cause irreversible illness or permanent injury as it deals only with data gathered and processed by regulated devices and viewed by a competent medical professional.

**Degree of influence on therapy or diagnosis:** The device does not control the delivery of energy, administration of parenteral drugs, or life-sustaining functions. It does not provide a diagnosis. It provides information/data only. It is a stand-alone system and not a part of a regulated classified device nor an accessory to it. Competent health professionals would reasonably be expected to exercise judgment in the use of the information.

The software is intended to provide the means for medical professionals to display data generated by medical scanning devices on a personal computer or workstation.

**Also see Appendix B for discussion of lossy image compression, example films and related data.**

## **8. Photographs**

See Section 4 for computer screen captures of principal views.

## **9. Device Description**

AMICAS is an integrated client-server software system designed to allow access to medical images by radiologists, referring physicians and other licensed professionals. This product is intended to allow the review of images on a digital Picture Archive and Communication System (PACS) network using a personal computer or workstation configured for standard Internet access. The server component of AMICAS is installed on a computer configured with connections to both the PACS and the Internet. Typically, images will be accessed through a World Wide Web (WWW) browser (the client) such as Microsoft Internet Explorer or Netscape Navigator. Radiology workstations can Query and Retrieve images from AMICAS using standard DICOM protocols.

AMICAS can be used for image distribution within a hospital, a managed care organization or an isolated imaging center. It can also serve as a telemedicine link between widely separate organizations.

A radiology imaging device such as a CT, MR or CR scanner on the PACS network of one institution can be linked to the display workstations on the PACS network of another institution via AMICAS servers on each of the PACS. The AMICAS servers communicate with each other via the public Internet or a private intranet.

See Section 2 for device description and Appendix C for a Feature Summary (page C-29).

The user's Web browser is a major component of the AMICAS system. Appendix C includes the Initial Configuration document (page C-24) which discusses the characteristics of specific Web browsers in relation to the functioning of the AMICAS system.

### **10. Comparison with Equivalent Devices**

AMICAS has **Indications for Use** similar to other medical image viewers such as Evergreen Technologies MedVision [ 510(k) Number K924178 ] or the RSTAR Image Management System [ 510(k) Number K943994 ]. AMICAS also shares with these devices a **Target Population** that is competent health professionals. Also equivalent to these devices, the AMICAS Design will operate with off-the-shelf hardware and systems.

Like the RSTAR Image Management System [ 510(k) Number K943994 ], AMICAS employs image compression to remove redundant or unimportant information in the original image data. The wavelet image compression libraries and default compression settings are believed to be substantially equivalent to the libraries used in the previously cleared product. Images showing the effect of compression are attached to this submission.

<b>Feature</b>	<b>MedVision [K924178]</b>	<b>RSTAR [K943994]</b>	<b>AMICAS</b>
<b>Indications for Use</b>	Similar	Similar	Similar
<b>Target Population</b>	Health Professionals	Health Professionals	Health Professionals
<b>Uses Off-the-Shelf Monitors</b>	YES	NO	YES
<b>Lossy Image Compression</b>	NO	YES	YES
<b>Lossy Compression Technology</b>	NO	Aware, Inc.	Aware, Inc.
<b>DICOM Acquisition</b>	YES	NO	YES
<b>TCP/IP Communications</b>	YES	YES	YES

**Tabular Comparison with Equivalent Devices**

### **11. Image Compression Technology**

AMICAS employs wavelet compression software supplied by Aware, Inc., Bedford, MA. This component, together with the input parameters that are determined by the Autocyt Group software (see Appendix B) are the principal determinants of image quality. Aware is also the supplier of compression technology used in the RSTAR [K943994] product to which we claim equivalence.

AMICAS has been developed and tested for over one year in collaboration with the Radiology Associates of Massachusetts General Hospital (MGH), Boston, MA. The founders of Autocyt Group have extensive experience with the design and implementation of systems that employ wavelet image compression. Adrian Gropper, M.D. has been a technical consultant to MGH for over 4 years and was the senior system architect of the RSTAR telemedicine system. Sean Doyle, AMICAS lead software developer, was Director of Software at RSTAR for the equivalent product.

The principal academic reference for clinical use of wavelet compression is:

Goldberg MA, Rosenthal DI, Chew FS, Blickman JG, Miller SW, Mueller PR. New high-resolution teleradiology system: prospective study of diagnostic accuracy in 685 transmitted clinical cases. *Radiology* 1993; 186: 429-434

## 12. Test Data and Conclusions

Appendix B presents typical performance data and includes original films as examples of device operation.

AMICAS automatically selects a target compression ratio based on the modality information supplied in the DICOM header of each image. This target compression ratio is based on three years of clinical experience with wavelet compression at Massachusetts General Hospital, Boston, MA and is consistent with the typical compression ratios used in the RSTAR Image Management System [510k Number K943994].

AMICAS target compression ratios are set to:

Modality	Target Compression Ratio based on Typical Information Content	Target Compression Ratio as Displayed to the User
CR	23:1	30:1
CT	11:1	15:1
MR	6:1	8:1

## 13. Software Information

See Sections 4 and 6 and Appendix D.

## 14. Confidentiality

Portions of the attached enclosure are confidential.

We would appreciate the earliest attention to this 510(k) submission. We are a small business and are depending on AMICAS sales. Please do not hesitate to contact me at 617-924-5329 or via pager at 617-362-8002 if you have questions regarding this submission.

Sincerely,



Adrian Gropper, M.D.

President  
enclosure