

K082144

SEP - 5 2008

AMICAS PACS 6.0 510(k)

---

**510(k) Summary of Safety and Effectiveness - as required by 21 CFR part 807.92**

Date prepared: July 24, 2008

Submitted by: AMICAS, Inc.  
20, Guest St.  
Suite 400  
Boston, MA 02135

Contact: Patrice JC Nedelec  
Contact email: [pnedelec@amicas.com](mailto:pnedelec@amicas.com)  
Contact Telephone: 617-779-7858 or 617-372-1331  
Contact Fax: 732-601-2512

Device Trade Name: AMICAS PACS 6.0  
Device Common Name: Picture Archiving Communication System (PACS)  
Regulation number: 892.2050  
Device Classification: Class II  
Name: AMICAS PACS  
Predicate Device: AMICAS Vision Series PACS 5.5  
Predicate Device Manufacturer: AMICAS Inc.  
20 Guest Street  
Boston, MA 021235

Predicate Device 510(k) number: K073526  
Date received: 12/17/2007  
Decision date: 03/12/2008  
Decision: Substantially equivalent  
Panel Code Device reviewed by: Radiology  
Panel Code Device classified by: Radiology  
Product Code: LLZ  
Regulation number: 892.2050  
Device Classification: Class II

**Device Description, intended use**

AMICAS PACS 6.0 is software intended to create and display two-dimensional and three-dimensional images of anatomy from a series of digitally acquired images. Typical users of AMICAS PACS 6.0 are radiologists, technologists and clinicians.

AMICAS PACS 6.0 is designed and marketed for soft copy reading, communication and storage of studies produced by digital modalities, to include Digital Mammography.

AMICAS PACS 6.0 receives images acquired from DICOM-compliant medical imaging systems, data from FDA-cleared Computer-Aided Detection systems and other FDA-cleared Image processing systems.

AMICAS PACS 6.0 imports images and render said images, upon request, within the viewer component utilizing both lossless (reversible) and lossy (irreversible) compression.

To support the diagnostic interpretation of Mammography studies, AMICAS PACS 6.0 will display the full fidelity DICOM image in a non-compressed format. Images will be rendered with patient and clinical information clearly displayed as part of the DICOM Overlay as required by MQSA, on monitors cleared by FDA for use in Digital Mammography. Lossy compressed mammography images and digitized film screen images must not be used for the purpose of primary diagnosis. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

Within AMICAS PACS 6.0, the AMICAS Real Time Worklist offers real-time status of radiology activity and provides customizable workflow management capabilities. Communication of critical results is facilitated and documented through optional, and configurable, components within the Real Time Worklist.

AMICAS PACS 6.0 also offers the Patient Dashboard which provides a single view of all patient data, both imaging and non-imaging.

AMICAS Reach is an optional component within AMICAS PACS 6.0 which provides clinicians secure, proactive communication and access to clinical reports and images.

Order and Report information generated by HIS/RIS and report creation systems are received and displayed in PACS via the transmission of HL7 messaging. For this data, AMICAS PACS 6.0 is not the creator, but instead the downstream recipient which relies on the validity of data from said systems.

AMICAS PACS 6.0 must be installed on suitable, commercial-standard hardware. It is the user's responsibility to ensure monitor quality, ambient light conditions and image compression ratios are consistent with the clinical application.

### **General Safety Considerations**

AMICAS PACS 6.0 software and the computer platform that it is installed on together constitute a system for the interpretation of medical image data by trained and qualified professionals. It is the user's responsibility to ensure that image quality, display quality, environmental lighting and other possible distractions are consistent with the clinical application. Refer to the instruction manuals for your specific computer and display hardware for information regarding installation, calibration and additional safety issues.

AMICAS PACS 6.0, as its predicate, includes tools for enlarging, highlighting and obscuring portions of an image relative to other portions. Inappropriate application of these tools can result in the obscuration of important anatomy and contribute to an erroneous interpretation. It is the user's responsibility to understand the effect of image manipulation tools and to apply in a manner consistent with the clinical application. The user must review the cautionary statements in the User's guide.

Be sure to limit access to patient data to authorized individuals who are fully trained and qualified to use this equipment.

### **Testing**

AMICAS PACS 6.0 is tested with reference to its Software Requirements Specifications, as documented in the Functional Verification Procedure included in this 510(k) filing.

Functional testing is an integral part of AMICAS, Inc. Product Development process known as "VDEV" (Vision Development Elaboration Validation), also documented in this filing (see part G section B).

Before undergoing Functional testing, a PACS application undergoes technical, lower-level testing known as "Unit Testing"; related verification, test cases and results are as well documented in this 510(k) filing (see part G section I).

Design Validation activities, as depicted in Part D of this filing, consist of testing in real-life client environments by Licensed Physicians, and address intended use, end-user expectations and experience.

The AMICAS Quality Department, per procedure, independently verifies completeness of all deliverables -to include testing reports and assessment of safety and effectiveness as well as Risk Analysis Record- before issuing a recommendation to release to Management.

### **Some more detail on CAD SR support and GSPS**

**CAD** (Computer Aided Detection), or more specifically "Mammo CAD Markers" are generated by 3rd party Medical Devices approved by FDA. They are in the form of non-image DICOM Structured Reports (S/R) and contain vector and text information that is rendered on the image, to show possible areas of concern. The workflow is that the images (study) are captured and imported into the AMICAS system from the imaging modality, and in parallel, the images (study) are also sent to CAD for processing. The output of these the CAD systems are non-imaging DICOM S/R files that also get imported into the AMICAS system.

When the user loads a study, we display the images as we normally do, and provide indicators on the images if these CAD are available. The CAD markers are not displayed initially, only after the user has viewed the images. These markers can be manually turned on.

**GSPS** (Grayscale SoftCopy Presentation State) is a non-image DICOM format. By default, the initial presentation state of images are derived from a limited number of DICOM tags (such as the initial Window/Level values, or LUT (look up table). GSPS is a much more general format, which provides for many presentation (rendering) parameters (window/level, LUTs, zoom/pan, invert, and orientation) as well as annotations. AMICAS PACS 6.0 uses GSPS objects for our native format, for the rendering parameters as well as annotations. It is possible to take our generated GSPS objects and use them to display it exactly as it appears in AMICAS PACS 6.0 on any DICOM compliant device, assuming it supports GSPS.

Mammography workstations were probably the first to start to use GSPS. It is also the basic of IHE CPI (Consistent Presentation of Images) Profile, so any DICOM device that generates GSPS object can be used as input into our server for studies we display.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP - 5 2008

Ms. Patrice J.C. Nedelec  
Director of Quality  
AMICAS, Inc.  
20 Guest Street Suite 400  
BOSTON MA 02170

Re: K082144  
Trade/Device Name: AMICAS PACS 6.0  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: July 28, 2008  
Received: July 30, 2008

Dear Ms. Nedelec:

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 (PMA), 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.

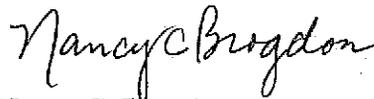
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.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

## Indications for Use

510(k) Number (if known):

Device Name: AMICAS PACS 6.0

Indications For Use:

AMICAS PACS 6.0 is designed and marketed for soft copy reading, communication and storage of studies produced by digital modalities, to include Digital Mammography.

AMICAS PACS 6.0 receives images acquired from DICOM-compliant medical imaging systems, data from FDA-cleared Computer-Aided Detection systems and other FDA-cleared Image processing systems.

AMICAS PACS 6.0 imports images and render said images, upon request, within the viewer component utilizing both lossless (reversible) and lossy (irreversible) compression.

To support the diagnostic interpretation of Mammography studies, AMICAS PACS 6.0 will display the full fidelity DICOM image in a non-compressed format. Images will be rendered with patient and clinical information clearly displayed as part of the DICOM Overlay as required by MQSA, on monitors cleared by FDA for use in Digital Mammography. Lossy compressed mammography images and digitized film screen images must not be used for the purpose of primary diagnosis. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

Within AMICAS PACS 6.0, the AMICAS Real Time Worklist offers real-time status of radiology activity and provides customizable workflow management capabilities.

Communication of critical results is facilitated and documented through optional, and configurable, components within the Real Time Worklist.

AMICAS PACS 6.0 also offers the Patient Dashboard which provides a single view of all patient data, both imaging and non-imaging.

AMICAS Reach is an optional component within AMICAS PACS 6.0 which provides clinicians secure, proactive communication and access to clinical reports and images.

Order and Report information generated by HIS/RIS and report creation systems are received and displayed in PACS via the transmission of HL7 messaging. For this data, AMICAS PACS 6.0 is not the creator, but instead the downstream recipient which relies on the validity of data from said systems.

AMICAS PACS 6.0 must be installed on suitable, commercial-standard hardware.

It is the user's responsibility to ensure monitor quality, ambient light conditions and image compression ratios are consistent with the clinical application.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

---

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



(Division Sign-Off)

Division of Reproductive, Abdominal and  
Radiological Devices

510(k) Number

    K082144