



JAN 14 1999

K983815

## 510(K) SUMMARY

K983815

**Submitter:** Dome imaging systems inc.

400 fifth avenue, Waltham, MA 02154

**Contact name:** Morteza Minaee

**Phone number:** (781) 895-1155

**Fax number:** (781) 895-1133

**Device trade name:** PACScache

**Product code:** 90LMD

**Legally marketed device to which Dome imaging systems inc., is claiming equivalence:** Amicas Web/Intranet Server (k970064) and RSTAR's Image Management System (K925994)

### ***Safety and Effectiveness Information***

PACScache 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.

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.

#### **List of hazards related to the functions performed by the software and means taken to mitigate these hazards:**

This product falls in the "Low 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:** The loss or corruption of patient demographics, study information and image data is the basic hazard related to any PACS.

Incorrect display of the image data is possible due to incorrect data produced

by the scanner or from a software malfunction. The mitigation is through the FDA's regulation of these devices, and through the QA system and the verification and validation test procedures adhered to during development and testing stages of the software product prior to its release. Additional control is the intended use of the product with properly regulated devices, and timely identification and correction of any potential software problems and subsequent testing procedures.

Among factors considered in this hazard analysis were the risk or danger to the patient. The software can not immediately threaten the patient's life nor directly cause any irreversible illness or permanent injury. It only deals with data gathered and processed by FDA regulated devices and viewed by a competent medical professional.

Degree of influence on therapy or diagnosis was also considered in the hazard analysis. The software product does not control the delivery of energy, administration of parenteral drugs, or devices with life-sustaining functions. It does not provide a diagnosis. It only provides information/data. It is a stand-alone system and not a part of a regulated classified device or accessory to it (It may be offered for use by OEM customers for integration into their product).

Competent health professionals would reasonably be expected to use judgement and professional expertise in the use and interpretation of the information.

PACScache has **Indications for Use** similar to other image viewing software products such as AMICAS (510k # k970064). It uses the same target end-users (competent health professionals). Also, as in the above claimed equivalent devices, it is designed to operate with off-the-shelf hardware and systems.

Like the RSTAR Image management system, it employs JPEG image compression to remove redundant or unimportant information in the original data. Autocyte group's AMICAS and RSTAR's Image Management System also utilize wavelet compression which has been found to be substantially equivalent to previously cleared devices using JPEG compression techniques.

The table in exhibit F of our submission compares PACScache to AMICAS. Although technical differences can be noted on the following comparison chart, we believe that these differences are minor and that none of them affect the safety and efficacy of the PACScache product.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Morteza Minaee  
Director, Quality Assurance  
Dome Imaging Systems®  
400 Fifth Avenue  
Waltham, MA 02451-8738Re: K983815  
PACScache  
Dated: October 21, 1998  
Received: October 28, 1998  
Regulatory class: II  
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Minaee:

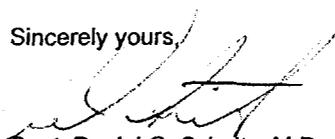
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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 (if known): k983815

Device Name: PACScache

Indication for use:

PACScache is an integrated client server software system designed to allow rapid access to radiographic data (specifically high resolution images) through out the radiology department as well as the entire hospital or clinical setting. The product is intended to enable review of images through clinical information systems and allow review of images on a digital picture archiving and communication system (PACS) network using a personal computer or workstation configured for standard internet access.

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\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use    
(Per 21 CFR 801.109)

OR

Over-The Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

David A. Segerson  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number k983815