SEP 2 1 2005

K052460

510(k) Summary of Safety and Effectiveness

Date: September 13, 2005

Submitter:
RamSoft Inc
16 Four Seasons Place, Suite 215
Toronto, ON M9B 6E5, CANADA

Contact Name: Vijay Ramanathan

Trade Names: PowerServer, PowerReader, Gateway, PowerCache

Common Name: Picture Archiving and Communication System (PACS)

Classification Name: LLZ – Image Processing System (892.2050)

Substantially Equivalent devices:
RamSoft PACS (RamSoft Inc) – K031562
Centricity PACS System (GE Medical Systems Information Technologies) – K043415

Description:
The PowerServer software suite is used on general purpose computing hardware and includes the following components: PowerServer, PowerReader, Gateway, and PowerCache. As long as minimum hardware and operating system requirements are met, the user or system integrator is free to choose his/her own hardware platform.

PowerServer is a scalable storage and distribution system for clinical images and data. Images can be stored in lossless or lossy formats. The system is DICOM compliant for image storage, archiving, retrieval, and transmission, and communicates with other DICOM devices. The system also communicates with PowerReader workstations and PowerCache servers. Acquired image data is preserved as captured and changes to display definitions are saved as presentation states so that images may always be reverted back to their initial state. PowerCache is a caching server that communicates with PowerServer and serves PowerReader workstations. A single PowerCache can serve multiple PowerReader workstations, reducing network traffic between PowerReader workstations and PowerServer.

PowerReader is a workstation that views, edits, manipulates, annotates, analyzes, stores, and distributes images and data stored on PowerServer and PowerCache. PowerReader can connect directly to PowerServer and can also connect via PowerCache. PowerReader provides the user with the ability to import, transmit, print, display, store, edit, and process medical images and data.

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Gateway is a stand-alone DICOM compliant workstation that views, edits, manipulates, annotates, analyzes, stores, and distributes images and data. Gateway provides the user with the ability to import, transmit, print, display, store, edit, and process medical images and data.

Intended Use:

This software is used with general purpose computing hardware for the storage, review, analysis, annotation, distribution, printing, editing, and processing of digital images and data acquired from imaging devices such as CR, CT, DX, MR, MG, NM, PT, RF, US, XA, film digitizers, and document scanners, and other DICOM devices. With appropriate hardware, the software is intended for use as a primary diagnostic, analysis, and review tool for use by trained healthcare professionals.

It is the user's responsibility to ensure image quality, lighting, and image compression ratios are suitable for the clinical application.

Digitized film should not be used for primary diagnosis in mammography. Lossy compression should not be used for primary diagnosis in mammography. Primary diagnosis on digital mammograms should not be done on any monitors other than those specifically cleared by the FDA for digital mammography applications. Film printing for digital mammography should not be performed on any printers other than those specifically cleared by the FDA for digital mammography applications.

Technology:
This device employs the same functional scientific technology as its predicate devices.

Test Summary:
This device complies with the voluntary standards as detailed in Section A.8 of the 510(k) submission. The following testing measures were applied to the development of this device:

- Hazard Analysis
- Requirements Reviews
- Design Reviews
- Code Reviews
- Unit Testing
- System Testing
- Validation Testing
- Performance Testing

Conclusion:
This device is as safe, as effective, and performs as well as predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1 2005

Mr. Vijay Ramanathan
President and CEO
RamSoft, Inc.
16 Four Seasons Place, Suite 215
Toronto, ON, M9B 6E5
CANADA

Re: K052460
Trade/Device Name: PowerServer, PowerReader, Gateway, and PowerCache
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 13, 2005
Received: September 14, 2005

Dear Mr. Ramanathan:

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/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

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): K052460

Device Names: PowerServer, PowerReader, Gateway, PowerCache

Indications for Use:

This software is used with general purpose computing hardware for the storage, review, analysis, annotation, distribution, printing, editing, and processing of digital images and data acquired from imaging devices such as CR, CT, DX, MR, MG, NM, PT, RF, US, XA, film digitizers, and document scanners, and other DICOM devices. With appropriate hardware, the software is intended for use as a primary diagnostic, analysis, and review tool for use by trained healthcare professionals.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

X

Prescription Use _____ -OR- Over-The-Counter Use _____

David K Symm

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052460