K080290

510(k) Summary
(per 21 CFR 807.92)

FEB 22 2008

I. **Applicant**:

American Radiologist Network, Inc.
2298 N.W. 60th Street
Boca Raton, FL.
33496, U.S.A

Contact Person: Neil Iyer, President & CEO
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II. **Device Name**

Proprietary Name:	xViewNet
Common/ Usual Name:	Picture Archiving and Communications System
Classification Name:	System, Image Processing, Radiological
Regulation Number:	892.2050
Product Code:	LLZ
Classification:	2

III. **Predicate Device**

The xViewNet PACS is substantially equivalent to the following predicate devices:

- iSite Radiology (K013630) from Stentor Inc.
- iPACS Prism (K030751) from Real Time Image Inc.

IV. **Intended Use of the Device**

The xViewNet software is intended as a display and analysis tool for the interpretation of diagnostic images by trained healthcare professionals, including radiologists, physicians, technologists, clinicians and nurses. It is also intended to provide access to covered entities for clinical review, throughout the healthcare facility and at the point of image acquisition.

This device is not intended for mammography use

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V. **Description of the Device**

xViewNet is a secured imaging system that is used to view, edit, manipulate, annotate, analyze, and store images and data that are stored and managed in the web-based RIS. This software-based product provides capabilities for the

acceptance, transmission, printing, display, storage, editing and digital processing of medical images and associated data.

Images sent to xViewNet are converted into formats suitable for viewing in its framework, and temporarily stored in a local cache memory. The algorithms used by xViewNet to view JPEG and JPEG 2000 images follow known and acceptable protocols. Changes may be made to the presentation of the images. These changes are saved as display definitions only and do not alter the acquired image pixel data. Any and all display definitions applied to an image can always be reversed to the acquired state.

The xViewNet software includes advanced visualization such as 3-D multi-planar reconstruction of the 2-D images.

xViewNet uses standard "off-the-shelf" PC hardware and communicates using the standard TCP/IP stack. The network hardware used to support the TCP/IP stack is superfluous to XViewNet.

VI. Technical Characteristics

- Support for the DICOM 3.0 file specification, including all standard classes and modalities (CR, CT, MR, NM, US, RF, SC, VL, etc.)
- Overview of study or series with different filter possibilities
- Interactive scrolling through picture series
- Thumbnail view of different picture series
- Tools freely configurable to the different mouse buttons
- Interactive change of W/L or W/C
- Picture zoom with pixel interpolation
- Magnifying glass
- Panning of pictures
- Shows modality-dependent DICOM header information in each picture
- Placing and show values of grey tones (numeric), distances and angles (graphic and numeric), text annotations, ellipses, polygons, and arrows
- Several picture series can be shown side by side
- Allocation of picture by free layout choice
- Turn picture, reflect picture and invert picture
- Fast Interactive 3D volume rendering
- Coronal, Axial and Sagittal views
- xViewNet is able to read and display the HUGO dataset
- Fast continuous looping display of images in a series (cine-loop) at various speeds: forwards, backwards, and bi-directional

- Linking and Unlinking of windows to coordinate actions (window/level, panning, zooming, etc)

VII. Testing

The xViewNet program complies with the voluntary standards as detailed in Section 9 of this submission.

The following quality assurance measures were applied to the development of the MedViewNet program:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module Verification)
- Integration testing (System Verification)
- Final Acceptance Testing (Validation)
- Performance Testing
- Safety Testing

American Radiologist Network certifies that the xViewNet software is designed, developed, tested and validated according to written procedures. These procedures identify individuals within the organization responsible for developing and approving product specifications, coding and testing, validation testing and field maintenance.

For details please see Section 16. Software, item 7. Verification & Validation Testing.

VIII. Safety and Effectiveness

There are no substantial differences between the xViewNet defined in this 510(k) submission and the stated predicate devices. They are similar to the technologies that are currently used in other similar medical devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

FEB 22 2008

American Radiologist Network, Incorporated
% Mr. James W. Monroe
Staff Engineer – Medical Devices
Intertek Testing Services NA, Incorporated
2307 East Aurora Road
Unit B7
TWINSBURG OH 44087

Re: K080290
Trade/Device Name: xViewNet PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 1, 2008
Received: February 4, 2008

Dear Mr. Monroe:

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 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

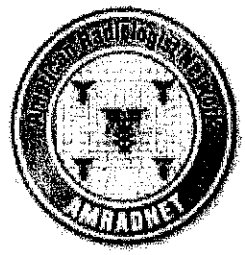
Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions 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

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): K080290

Device Name: xViewNet

Indications for Use:

xViewNet is a secured imaging software system that receives medical images and data from various imaging sources. Images and data can be stored, communicated, processed and displayed within the system and or across computer networks at distributed locations.

This device is not intended for mammography use

Prescription Use _X_ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K080290