9 510(k) Summary

9.1 Name and Address of Manufacturer

Xoran Technologies, Inc.

309 North First Street
Ann Arbor, MI 48103

Phone: (734) 663 7194
Fax: (734) 663 8500

9.2 Contact Information

Amy Kim
Regulatory Affairs Manager

(734) 663 7194

Date of Submission: November 15, 2007

9.3 Product Identification

Trade Name:	XoranConnect™
Common Name:	PACS
Classification:	Class II, Product code LLZ (Image Processing System - PACS, Sec. 892.2050).
Guidance Document:	Guidance for the Submission Of Premarket Notifications for Medical Image Management Devices (July 27, 2000)

9.4 Substantially Equivalent (Predicate) Devices

XoranConnect™ software is substantially equivalent to the following predicate devices:

Visage PACS/CS (Mercury Computer Systems, Inc.), K072205

NovaPACS (NovaRad Corporation), K061920

9.5 Device Description

XoranConnect™ is a web-based service designed to complement point-of-care medical imaging systems by providing point-of-expertise viewing and interpretation tools. XoranConnect™ runs on standard off-the-shelf PC and networking hardware, all of which has been manufactured by third party reputable manufacturers.

The system performs these major functions.

- Off-site data storage allows user studies to be stored off-site.
- Study viewer allows studies to be visualized and manipulated in 3D, multiplanar and other forms.

To accommodate the major functions, the overall system architecture includes the following distinct components:

- XoranVault™ storage system (storage servers, dispatcher)
- XoranConnect™ viewing system (study server, web server, web client)

The storage (backup) system consists of one or more servers designed to store and serve stored imaging content on a RAID5 storage device. Imaging modality negotiates the connection and transfers study to the storage server.

Once stored, imaging data is ready to be served to the requesting clients. When a user logs into the system by visiting a XoranConnect web page, study server begins to serve the data, which in turn is displayed in the user's web browser window. Any storage server may simultaneously serve multiple requests for images.

It is the user's responsibility to ensure that the appropriate PC hardware and display device are used to run the XoranConnect™ software application. XoranConnect™ requires at all times an active Internet connection to operate. It is the user's responsibility to ensure that the connection that is being used provides the speed, stability and reliability required to utilize XoranConnect™ for any given purpose or application.

9.6 Intended Use

XoranConnect™ is a web-based service designed to complement point-of-care medical imaging systems by providing point-of-expertise tools for viewing, interpretation, annotation, clinical review, analysis, distribution, processing and printing. Primary components include online multiplanar image viewing, offsite data storage, administrative reporting tools, and teleradiology workflow. It is intended as an extension to (but not limited to) the MiniCAT™ and xCAT™ CT imaging devices.

9.7 Comparison With the Predicate Devices

XoranConnect™ has the same indication for use as the predicate devices and they perform very similar functions. Apart from differences in menus, usability, specific tool implementations, appearance and price, all of XoranConnect™ functions can be found in at least one of the predicate devices (most likely both). All three devices perform similar functions, while the predicate devices have many additional features.

9.8 Conclusion

Functionality that XoranConnect™ provides is found on both predicate devices, and is therefore substantially similar to the predicate devices Visage PACS/CS (Mercury Computer Systems, Inc.), K072205, and NovaPACS (NovaRad Corporation), K061920. This design complies with 21 CFR 892.2050 and does not pose new safety risks.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 7 2008

Amy S. Kim, DDS
Regulatory Affairs Manager
Xoran Technologies, Inc.
309 N First Street
ANN ARBOR MI 48103

Re: K073306
Trade/Device Name: XoranConnect™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 21, 2007
Received: November 30, 2007

Dear Dr. Kim:

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

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): K073306

Device Name: XoranConnect™

Indications for Use:

XoranConnect is a medical imaging software system intended to display, edit, review, store, print and distribute images acquired from imaging devices such as Computed Tomography (CT), Magnetic Resonance (MR), Computed Radiography (CR), Ultrasound (US), Nuclear Medicine (NM), and other devices.

Prescription Use ___X___ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K073306

Division Sign-Off

510(k) _____