

K082240

510(k) Summary of Safety and Effectiveness

NOV 20 2008

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:
August 2, 2008

Submitter's Information: 21 CFR 807.92(a)(1)
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Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	SntryPACS™
Common Name:	Picture Archiving Communications System
Classification Name:	system, image processing, radiological
Product code:	LLZ
Device Classification:	892.2050

Predicate Device: 21 CFR 807.92(a)(3)

Edge PACS™ is substantially equivalent to:	
Manufacturer:	Voyager Imaging
Device Name:	Voyager PACS System
510(k) Number:	K062062
Product Code:	LLZ
Device Classification Name:	SYSTEM, IMAGE PROCESSING, RADIOLOGICAL
Regulation Number:	Class II - 892.2050

Device Description: 21 CFR 807.92(a)(4)

SntryPACS Server is a fully integrated DICOM Storage and DICOM Application Server, compatible with any DICOM modality and most DICOM viewing workstations.

SntryPACS server runs under the QStar storage server environment and provides PACS services such as storage provider and query retrieve provider. Both of these services runs as Linux daemons and utilizes DBMS system and file indexers for managing the medical images and reports. A typical SntryPACS network consists of a central SntryPACS server which stores a database containing the images, and of multiple clients that can retrieve and display these images on medical imaging software. The images are stored in DICOM format. The modalities (MRI, CT, PET, Ultrasounds, etc.) send the images to the PACS Server by using a DICOM "push" (DICOM C-Store). The server and the client workstations communicate by using the DICOM protocol (DICOM C-Store or Query & Retrieve). The clients display the images by using medical imaging software such as a DICOM viewer or a radiology review workstation client software system.

Key features

- Central storage server with complete DICOM protocol support to handle all different types of DICOM images and reports.
- Web-based user interface for system administration.

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- Fast transfer and access time (limited by the network bandwidth) for store and retrieval.
- Supports patient root and study root query retrieval.
- Support concurrent storage and retrieval of multiple modalities and clients.
- Provides scalable storage architecture for images/report data and includes support for removable media solutions.

Indications for Use: 21 CFR 807 92(a)(5)

SntryPACS™ is a device that receives digital images and data from various sources (i.e. CT scanners, MR scanners, ultrasound systems, R/F Units, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways, etc.). Images and data can be captured, stored, communicated, processed and displayed within the system and or across computer networks at distributed locations. SntryPACS™ can be integrated with an institution's existing Hospital Information System (HIS) or Radiology Information System (RIS) providing access to reports for fully-integrated electronic patient records. Typical users of the system are trained medical professionals (e.g. physicians, radiologists) Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretation. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

Technological Characteristics: 21 CFR 807 92(a)(6)

SntryPACS™ is a device that does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for SntryPACS™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device. The subject device has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

NOV 20 2008

QStar Technologies, Inc.
c/o Mr. Herman Oosterwijk
Consultant
OTech, Inc.
1600 Manchester Way
CORINTH TX 76210

Re: K082240

Trade/Device Name: SntryPACS
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 11, 2008
Received: November 17, 2008

Dear Mr. Oosterwijk:

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 Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(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 Biometrics' (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,



Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

(Indications for Use Form)

510(k) Number: K082240

Device Name:

Indications for Use:

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND

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

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