K081948

1. 510(k) Summary

SEP 19 2008

1.1 510(K) Owner Information (807 92(a)(1))

Summary Preparation Date:	April 2, 2008
Company Identification:	RAYPAX Inc. 14251 E. Firestone Blvd La Mirada, CA 90638
Contact Person:	Chris Chung 14251 E. Firestone Blvd La Mirada, CA 90638 Phone: (562) 921-8640 Fax: (626) 270-4099 Email:chris@raypaxusa.com

1.2 Device Identification (807 92(a)(2))

Device Trade Name:	RAYPAX System
Common/Usual Name:	Picture Archiving and Communications System (PACS)
Classification Names:	System, Image Processing, Radiological
Regulation Medical Specialty:	Radiology
Product Code:	LLZ
Regulation Number:	892.2050
Device Class:	2

1.3 Predicative Device Information (807 92(a)(3))

510(k) Number	K043415
Device Name	CENTRICITY PACS SYSTEM
Applicant	MEDICAL SYSTEMS INFORMATION TECHNOLOGIES
Regulation Number	892.2050
Classification Product Code	LLZ
Date Received	12/13/2004
Decision Date	01/21/2005
Decision	Substantially equivalent (SE)
Classification Advisory Committee	Radiology

1.4 Device Description (807 92(a)(4))

The RAYPAX System is a complete PACS package to receive medical images from medical modalities, and distribute medical images and reports to enable medical staff to verify, diagnosis, and refer them in multi medical facilities. It consists of RAYPAX PACS server, Getaways and Clients.

1.4.1 RAYPAX PACS Server

RAYPAX PACS server stores the images and information obtained from the medical equipments and other systems, and provides a connection for RAYPAX client to access the information depending on their previledge level. Remote access through the Internet is allowed, and to ensure a secure data transfer, strong data encryption(SSL) is provided. All DICOM images acquired in the RAYPAX System are stored unaltered and all display manipulations and annotations are stored as presentation parameters and they do not alter the original image file.

1.4.2 RAYPAX Gateways

RAYPAX Gateways communicate with medical modalities and other systems to receive and share image data, patient demographics, order schedule and study results. DICOM Gateway gathers medical exams from modalities and other system in DICOM format. Remote exams are gathered by Net Point or Lite locally and sent to PACS server through the internet. HL7 Gateway exchanges the patient and order information, study results with other information system in HL7 standard.

1.4.3 RAYPAX Clients

The clients of RAYPAX System are intended for diagnostic and analysis by trained healthcare professionals, including radiologists, physicians, technologists, clinicians and nurses. RAYPAX Clients connect the PACS server and enables medical staff to view medical data and assign special tasks in the PACS workflow.

QCW is a verification tool for a technician to reconstruct, verify exams. DW (Diagnostic Workstation) and RW (Review Workstation) are for the radiologist to perform diagnostic analysis of the exams. TW (Transcription Workstation) is a tool for the trancriptionist to create a preliminary report. WCC (Web Client Component) is a radiology referring tool for a physican to refer exam and report viewing at remote site. Net, Exp and Web versions of RAYPAX clients are intended to offer a remote access to the images through the Internet.

For PACS administrators, Admin provides with user management, server parameter setting, and Net Monitor provides the status of the PACS system and the performance of the medical organization.

1.5 Intended Use (807.92(a)(5))

510(k) Number (if known):
Device Name: RAYPAX System

The RAYPAX System is intended for the storage, reading, diagnostic review, analysis, annotation, distribution, printing, editing, and processing of digital images acquired from devices such as Computed Tomography (CT), Magnetic Resonance (MR), Computed Radiography (CR), Digital X-Ray (DX), Digital Mammography (MG), Ultrasound (US), Nuclear Medicine (NM), Positron Emission Tomography (PET), X-Ray Angiography (XA), Film Scanners, and any other DICOM supporting devices.

The clients of RAYPAX System are intended for diagnostic and analysis tool by trained healthcare professionals, including radiologists, physicians, technologists, clinicians and nurses. QCW (Quality control Workstation) is intended to verify exams. DW (Diagnostic Workstation) and RW (Review Workstation) is intended for radiologists to diagnostic analyze exams and WCC (Web Client Component) is intended for clinical review of physicians. Net Point and Lite are intended to acquire exams from local modalities and send the exams to the PACS server through the Internet. Net, Exp and Web versions of RAYPAX clients are intended to offer a remote access to the images through the Internet.

For the digital mammography images, to be viewed for primary interpretation, images must be acquired from an FDA approved Mammography device for primary interpretation and viewed on a display system with at least 5 Mega Pixel of resolution and has been cleared by the FDA for diagnosis of digital mammography images. Furthermore, the Mammography device must be able to provide, to the RAYPAX System, a viewable DICOM 'for presentation' mammography image. Images that are printed to film must be printed using a FDA approved printer for the diagnosis of digital mammography images.

1.6 Technological Characteristics (807.92(a)(6))

RAYPAX System is a standalone software package based on standard Microsoft technology, general purpose software and hardware platform. As a development tools, industry standard programming languages (C#, C++, and ASP) and the Microsoft Visual Studio are used. To create remote applications, web protocols and Microsoft Dot NET framework are used.

RAYPAX System is a DICOM 3.0 compliant system to receive images from medical device, and supports HL7 (Health Level Seven) to communicate with other information system. The system only uses IP address on LAN (Local Area Network) environment to communicate with medical device, and it has no contact with patient, nor does it control any life sustaining device.

All display manipulations and annotations in RAYPAX clients are stored as presentation parameters not to alter the original image file, so all DICOM images acquired in the RAYPAX System are stored and unaltered.

1.7 Substantial Equivalence Discussion (807.92(b)(1))

The predicative device and the RAYPAX System present similar indication for use statements. The Centricity PACS and RAYPAX System are Picture Archiving and Communication System. They are used to manage medical images and data, images are acquired from devices through the DICOM standard, and both systems are used by trained healthcare professionals for diagnosis.

Both the predicative device and the RAYPAX system employs a database, an image storage, HL-7 interfacing and DICOM services. Images are acquired into the system from DICOM supporting devices. So, the predicative device and the RAYPAX System have no contact with the patient, nor does it control any life sustaining device. A physician, providing ample opportunity for competent human intervention interprets images and information being printed.

The RAYPAX System is as safe, as effective, and performs as well as the predicate devices. Any differences between the RAYPAX system and the substantially equivalent system have no significant influence on safety and effectiveness.

1.8 Conclusion 807.92(b)(3)

We believe that The 510(k) Pre-Market Notification for RAYPAX System contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device. RAYPAX System has been and will be manufactured in accordance with the mandatory and voluntary standards listed in this submission. The submission contains the result of the hazard analysis that there is no software component in the RAYPAX System that we know of whose failure or design flaw would result in death of injury to a patient, and the "Level of Concern" of the RAYPAX System is "minor".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 2008

Mr. Chris Chung
Engineer
RAYPAX, Inc.
14251 E. Firestone Blvd.
LA MIRADA CA 90638

Re: K081948
Trade/Device Name: RAYPAX System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 27, 2008
Received: July 8, 2008

Dear Mr. Chung:

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 Statement

510(k) Number: K081948
Device Name: RAYPAX System

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Prescription Use ✓ 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 K081948