K050298

FEB 2 8 2005

510(k) Summary of Safety and Effectiveness

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

Date Prepared: February 1, 2005

Submitter's Information: 21 CFR 807.92(a)(1)

RealTimeImage Inc.
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1111 Bayhill Dr, Suite 290
San Bruno, CA 94066
Tel: 650.616.4671

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	iPACS Prism-5.0™
Common Name:	Picture Archiving Communications System
Device Classification:	892.2050 LLZ
Name:	System, Image Processing

Predicate Device: 21 CFR 807. 92(a)(3)

Device Classification Name	SYSTEM, IMAGE PROCESSING, RADIOLOGICAL
Regulation Number	892.2050
510(k) Number	K030751
Device Name	iPACS Prism
Applicant	RealTimeImage Inc.
Product Code	LLZ

Device Description: 21 CFR 807 92(a)(4)

iPACS Prism-5.0 is a modified version of iPACS Prism (K030751). Both devices are picture, archiving and communications system software applications from RealTimeImage.

The main significant difference between the modified device and the predicate device is that the modified device will now allow display of presentation quality digital mammography images, sent via the DICOM standard in order to make viewing of these images more convenient for the user.

Both systems are a complete PACS solutions designed to be Internet friendly for easy deployment over local area networks and/or wide area networks. IPACS Prism-5.0 is modular and will be offered under different brand names depending upon customer implementation and which system components of iPACS Prism-5.0 are needed The system is modular and will be offered under different brand names depending upon customer implementation and which system components of iPACS Prism are needed. iPACS™ handles various images and data objects in a Picture Archive and

Communication System (PACS) environment. These objects can be images, requests, patients, examination etc. PACS transmits digital electronic images and generates reports over a high-speed network to centralized storage. After transmission, patient information and images are available throughout the facility to many users simultaneously.

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

iPACS Prism-5.0™ is a device that receives medical images, (including mammographic 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.

iPACS Prism-5.0TM only supports lossless compression for primary mammography image interpretation. Lossy compressed or digitized screen film mammographic images must not be reviewed for primary image interpretations.
Only FFDM manufacturer processed images in DICOM "For Presentation" format can be displayed for primary interpretation. Mammographic images must only be interpreted using a FDA approved monitor that offers at least 5Mpixel resolutions and other technical specifications reviewed and accepted by the FDA.
Typical users of this system are trained professionals, including physicians, nurses, and technicians.

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

The device is medical device image management and processing software that is used with computer hardware in a picture archiving and communications system user environment. The device 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 iPACS Prism-5.0™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device. The system has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The submission contains the results of a hazard analysis and the potential hazards have been classified as Minor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2005

Real Time Image, Inc.
% Mr. Carl Alletto
Official Correspondent
OTech, Inc.
1600 Manchester Way
CORINTH TX 76210 USA

Re: K050298
Trade/Device Name: iPACS Prism-5.0™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: February 1, 2005
Received: February 7, 2005

Dear Mr. Alletto:

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

RealTime
Image

(Indications for Use Form)

510(k) Number: K050298

Device Name: *iPACS Prism-5.0™*

Indications for Use:

iPACS Prism-5.0™ from Real Time Image Inc. is a device that receives medical images, (including mammographic 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.

iPACS Prism-5.0TM only supports lossless compression for primary mammography image interpretation. Lossy compressed or digitized screen film mammographic images must not be reviewed for primary image interpretations. Only FFDM manufacturer processed images in DICOM "For Presentation" format can be displayed for primary interpretation. Mammographic images must only be interpreted using a FDA approved monitor that offers at least 5Mpixel resolutions and other technical specifications reviewed and accepted by the FDA.

Typical users of this system are trained professionals, including physicians, nurses, and technicians.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050298