K061972

510(k) Summary of Safety and Effectiveness

SEP 18 2006

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

Date Prepared: June 30, 2006

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

Connect Imaging Inc.
Philip J. Manly, President
850 W. Hind Drive #116
Honolulu, HI 96821
Tel: 808-373-7048

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

Trade Name:	Connect Imaging PACS
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:	K031704
Device Name:	FilmLess Clinic
Applicant:	Connect Imaging Inc.
Product Code:	LLZ

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

Connect Imaging PACS is a modified version of Connect Imaging FilmLess Clinic (K031704). Both devices are picture, archiving and communication system software applications from Connect Imaging Inc.

The main 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 the viewing of these images more convenient for the user.

Both systems are a complete PACS solution designed for deployment over local area networks, wide area networks, or through web access.

Connect Imaging PACS is modular and will be offered under different brand names for different modular parts of the PACS. The Connect Imaging PACS handles various images and data objects in Picture Archiving and Communications System (PACS) environment. The Connect Imaging PACS received digital images in DICOM format from DICOM compliant modalities, as well as digitized analog images using film digitizers that are 510(k) approved. These images are stored in a central archive and distributed to various locations for viewing with an imaging workstation.

Indications for Use: 21 CFR 807.92(a)(5)

Connect Imaging PACS is a device intended to provide capability for the acceptance, transfer, display, storage, digitization and digital processing of medical images via the DICOM standard protocol.

Options allow for additional capability, including transmission of images, digitization of film images, acceptance of digital images directly from different medical image modalities, and quality review of images.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specification reviewed and accepted by FDA.

Connect Imaging PACS is intended for use by qualified physicians and radiologists and other trained personnel such as technologists and nurses.

Technological Characteristics: 21 CFR 807.92(a)(6)

The device is a medical device imagement and processing software that is used with computer hardware in a picture archiving and communication 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 Connect Imaging PACS contains adequate information and data to enable the FDA – CDRH to determine substantial equivalence to the predicate device.

The Connect Imaging PACS 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

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 18 2006

Mr. Philip J. Manly
President
Connect Imaging, Inc.
850 W. Hind Drive, #116
HONOLULU HI 96821-1855

Re: K061972
Trade/Device Name: Connect Imaging PACS
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 30, 2006
Received: July 27, 2006

Dear Mr. Manly:

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.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). 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): K061972

Device Name: Connect Imaging PACS

Indications for Use:

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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)

Carolyn Y Neuland for N Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061972