K033624

Canon

CANON U.S.A., INC.
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DEC 15 2003

510(k) Summary

Submitter:	Canon U.S.A., Inc. Canon Medical Systems Division 15955 Alton Parkway Irvine, CA 92618
Contact person:	Sean M. Curry 16787 Bernardo Center Drive, Suite A1 San Diego, CA 92128
Phone:	(858) 675-8200
FAX:	(858) 675-8201
Proprietary name:	PACS Software Solution 2003
Common name:	Picture Archiving and Communication System (PACS)
Classification:	892.2050
Product Code:	LLZ
Classification name:	System, Imaging Processing, Radiological

Substantial equivalence claimed to:
K940664: Paper Film – PACS

Description:

PACS Software Solution 2003 (PSS03)[i] is proprietary software used in conjunction with computer hardware to provide a Picture Archiving and Communication System. PSS03 has been designed to manage medical imaging data from various imaging devices (e.g. Magnetic Resonance Imaging, Computerized Tomography, Digital Radiography, Ultrasound, etc.). Management of medical imaging data from these devices, enabled by PSS03, includes display tools, the support of industry standard communication protocols (e.g. Transfer Control Protocol/Internet Protocol, Digital Communication in Medicine, Ethernet, etc.) and archiving of data using hierarchical protocols. The system provides redundant storage of the exam data.

PSS03 accommodates individual user preferences by automatically displaying medical images in a presentation format unique to the user and to the type of exam selected.

[i] All referenced product names mentioned throughout this document, and other marks, are or may be trademarks of their respective owners.

PSS03 is highly scalable, providing a small facility or a large enterprise of facilities the same functionality.

Intended use:

PACS Software Solution 2003 (PSS03) is intended to be used by radiologists and other medical professionals to display medical images on digital display devices or hard copy printers. For purposes of diagnosis, or for clinical review, PSS03 provides an efficient user interface. Additionally, PSS03 manages the archiving of medical images for short and long term storage using off-the-shelf hardware. PSS03 in intended to be used with imaging equipment (e.g., Magnetic Resonance Imaging (MRI), Computerized Tomography (CT), Digital Radiography (DR), Ultrasound (US), etc.) and patient information systems (e.g., Hospital Information Systems (HIS), Radiology Information Systems (RIS)) approved for medical use.

Summary of technological characteristics in comparison to predicate device:

The PACS Software Solution 2003 and the Paper Film – PACS, are Picture Archiving and Communication Systems (PACS) that operate under Open Windows on a Unix based operating system. They both consist of one or more of the following: image server, database server, and workstations for acquiring, processing, rendering, evaluating, archiving, printing and distributing images. PACS Software Solution 2003 has been updated to take advantage of newer faster systems such as monitor resolution and tape drives as well as allowing for multiple external storage devices.

The viewing applications in both systems provide "smooth" and "sharp" filtering of images. A low-pass blurring kernel is used for smoothing. Both systems also utilize 8 bit and 12 bit compression using JPEG format.

The new system ensures patient integrity by assigning a Radiology Information System key to each exam, in addition to the Medical Record Number and the patient's name (which was used with the predicate device).

As with the predecessor, the PACS Software Solution 2003 display devices are calibrated using a standard SMPTE pattern and/or calibration software provided by the graphics card supplier.

The PACS Software Solution 2003 system has the same Indications for Use, equivalent design features, methods of use, and equivalent functional characteristics as the predicate device and therefore raises no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2003

Canon U.S.A., Inc.
% Mr. Sean Curry
Chief Operating Officer
Certified Software Solutions, Inc.
16787 Bernardo Center Drive, Suite A1
SAN DIEGO CA 92128

Re: K033624
Trade/Device Name: PACS Software Solution 2003
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: November 11, 2003
Received: November 18, 2003

Dear Mr. Curry:

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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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/dsma/dsmamain.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

510(k) Number (if known): K033624

Device Name: *PACS Software Solution 2003*

Indications for Use:

PACS Software Solution 2003 is used to acquire, process, display, evaluate, archive, print and distribute DICOM compliant images for clinical purposes. Images may be acquired from imaging modalities such as CR, CT, MR, X-Ray, and other devices.

(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)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033624