510(K) SUMMARY

[as required by 807.92(c)]

JUL - 7 2009

A. 510k Number: K083658

B. Applicant:

Company name: Medical Standard Co.,Ltd
Address: Hanyang Institute of Technology 17, Haengdang-dong Sungdong-ku Seoul, Korea, 133-791
Tel.: +82.2.2282.6600 (ext: 303)
Dir: +82-2-2282-6667
Fax: +82.2.2282.6690
Email: mike@medicalstandard.com

C. Proprietary and Established Names: Medical Standard Inc.

D. Regulatory Information

Device Classification Name	System, Image Processing, Radiological
Regulation Number	892.2050
Device Name	PACS Plus 5th edition
Applicant	Medical Standard Co. Ltd.
Product Code	LLZ

E. Intended use

PACS PLUS 5th EDITION is software that receives digital images and data from various sources (e.g. CT scanners, MR scanners, ultrasound systems, R/F Units, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways or other imaging sources). Images and data can be stored, communicated, processed and displayed within the system and or across computer networks at distributed locations.

Options make possible reading (including mammography), telecommunications; fast demonstration; etc.; and teleconferencing.

Lossy compressed mammographic images are not intended for diagnostic review. Mammographic images should only be viewed with a monitor approved by FDA for viewing mammographic images.

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

F. Device Description

PACSPLUS 5TH Edition™ makes possible the capturing, storage, distribution, and networking of medical images at distributed locations. In cases where DICOM images are not directly available to *PACSPLUS 5TH Edition* ™, the system can acquire medical images using a DICOM gateway, which generates DICOM-type files. For example, film digitizers obtain images from old film and convert them to meet DICOM standards and stored. Stored files are transmitted using a network and can be viewed or manipulated from an imaging workstation.

G. Substantial Equivalence Information

1. Predicate Device – K042311

Device Classification Name	System, Image Processing, Radiological
Regulation Number	892.2050
Device Name	PACS Partner
Applicant	Medical Standard Co. Ltd.
Product Code	LLZ

2. The 510(k) Pre-Market Notification for PACS Plus 5th edition contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.

PACS Plus 5th edition 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 "Level of Concern for potential hazards has been classified as "Minor".

H. Standard / Guidance Document Referenced (if applicable)

Digital Imaging and Communications in Medicine (DICOM) Standard;

Joint Photographic Experts Group (JPEG) Standard,

Society of Motion Picture and Television Engineers (SMPTE) Test Pattern

I. Performance Characteristics (If/when applicable)

PACS Plus 5th edition is a software product that handles digital medical images. 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medical Standard Co., Ltd.
% Mr. Brandon Choi
Official Correspondent
PATS Corporation
49 Candlewood Way
BUENA PARK CA 90621

JUL - 7 2009

Re: K083658
Trade/Device Name: PACS PLUS 5th EDITION Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 6, 2009
Received: May 22, 2009

Dear Mr. Choi:

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 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Janine M. Morris
Acting 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): K083658

Device Name: PACS PLUS 5th EDITION software by Medical Standard Co. Ltd

Indications For Use:

PACS PLUS 5th EDITION is software that receives digital images and data from various sources (e.g. CT scanners, MR scanners, ultrasound systems, R/F Units, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways or other imaging sources). Images and data can be stored, communicated, processed and displayed within the system and or across computer networks at distributed locations.

Options make possible reading (including mammography), telecommunications; fast demonstration; etc.; and teleconferencing.

Lossy compressed mammographic images are not intended for diagnostic review. Mammographic images should only be viewed with a monitor approved by FDA for viewing mammographic images.

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

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 K083658