K042311

PACS www.pacspartner.com

SEP - 9 2004

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:
August 2, 2004

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

YoungJin Hong
Technical Manager
Medical Standard Co. Ltd.,
Hanyang Institute of Technology 17,
Haengdang-dong Sungdong-ku Seoul,
Korea, 133-791

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

Trade Name:	PACSPartner™
Common Name:	Picture Archiving Communications System
Device Classification:	892.2050
Name:	System, Image Processing

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

Device Classification Name	system, image processing, radiological
510(k) Number	K023460
Regulation Number	892.2050 Class II
Device Name	PACSPlus™
Applicant	Medical Standard Co. Ltd.,
Product Code	LLZ
Decision Date	01/09/2003
Decision	Substantially equivalent (SE)
Classification Advisory Committee	Radiology
Review Advisory Committee	Radiology
Type	Traditional

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

PACSPartner™ makes possible the capturing, storage, viewing, distribution, and networking of medical images at distributed locations. In cases where DICOM images are not directly available, 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.

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

PACSPartner™ 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 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 specifications reviewed and accepted by FDA Typical users of this system are trained professionals, physicians, nurses, and technicians.

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

PACSPartner™ 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.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for PACSPartner™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.

PACSPartner™ 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".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Medical Standard Co., Ltd.
% Mr. Ned Devine
Responsible Third Party Official
Entela, Inc.
3033 Madison Ave., SE
GRAND RAPIDS MI 49548

Re: K042311
Trade/Device Name: PACSPartner™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: August 24, 2004
Received: August 26, 2004

Dear Mr. Devine:

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

(Indications for Use Form)

510(k) Number: **K042311**

Device Name:
PACSPartner™ software by Medical Standard Co. Ltd.

Indications for Use:

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

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Feigal

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042311