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510(k) Summary

DEC 1 6 2008

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: Nov. 5, 2008

1. Company and Correspondent making the submission:

Name – EMSOMA Co., Ltd.
Address – #302 Kang-rim B/D, Sungnae-dong 448-7, Gangdong-gu, Seoul, 134-030, Korea
Telephone – +82-2-3462-2008
Fax – +82-2-3462-2088
Contact – Mr. WeonBum, Lee
Internet – http://www.emsoma.com

2. Device :

Trade/proprietary name	: PetaVision
Common Name	: Picture archiving and communication system(PACS)
Classification Name	: Imaging Processing System, Radiological

3. Predicate Device :

Manufacturer	: Mediface Co., Ltd.
Device	: MEDIFACE PACS
510(k) Number	: K010259(Decision Date - Jan. 29. 2001)

4. Classifications Names & Citations :

21CFR 892.2050, LLZ, Imaging Processing System, Radiological, Class2

5. Description :

5.1 General

PetaVision™ is PACS (Picture Archiving and Communication System) software for

radiologist and physician doctor. By use of PetaVision™ enables images such as x-ray and scans to be stored electronically and viewed on screens. Doctors and other health professional can access and compare images at the touch of a button

Also, PetaVision™ is a device that provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images. The software components provide functions for performing operations related to image manipulation, enhancement, compression or quantification. And Images may be acquired from imaging devices such as CR, CT, MR and other devices.

The main functions of PetaVision™ are as follows.

5.2 Main Function

1) Image Acquisition

It acquires DICOM Image that is transmitted in the form of DICOM Protocol from each of various modalities and loads such data, corresponding to that image, into Database.

2) Worklist

Worklist contain patients name, sex, patients ID, Study date, Study description, concerned clinic department, name of doctor, reading results and thumbnail image. It shall be available at user's sort out, adjust the size of columns.

3) Reading

Report makes it possible to make a report more easily by using intuitive user interface. Radiology doctor has the right to approve or to modify the report before approved.

4) DICOM image display

Image display mode is most general one that simulate as if film is read at the film view box. Cine View Mode can show a series of images, as seeing movie with a certain focused area fixed in a certain time interval for reading. Cine View Mode is very helpful in reading a series of images acquired from like MRI and CT modality.

5 Indication for use :

The PetaVision is a device that provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images. The software components may provide functions for performing operations related to image manipulation, enhancement, compression or quantification. And Images may

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be acquired from imaging devices such as CR, CT, MR and other devices. This device is not intended for mammographic applications.

6 Comparison with predicate device :

EMSOMA Co., Ltd., believes that the Picture archiving and communication system(PetaVision) is substantially equivalent to the MEDIFACE PACS of Mediface Co., Ltd..

8. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification EMSOMA Co., Ltd. concludes that The PetaVision is safe and effective and substantially equivalent to predicate devices as described herein.

9. EMSOMA Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2008

EMSOMA Co., Ltd.
% Mr. Marc M. Mouser
CAS Manager II/Office Coordinator
Underwriters Laboratories, Inc.
2600 NW Lake Road
CAMAS WA 98607

Re: K083555
Trade/Device Name: Picture archiving and communication system (PACS)/ PetaVision
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 6, 2008
Received: December 2, 2008

Dear Mr. Mouser:

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 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). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Joyce M. Whang, Ph.D.
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):

Device Name: Picture archiving and communication system (PACS)/ PetaVision

Indications for Use:

The PetaVision is a device that provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images. The software components provide functions for performing operations related to image manipulation, enhancement, compression or quantification. And Images may be acquired from imaging devices such as CR, CT, MR and other devices. This device is not intended for mammographic applications.

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 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)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K083555