



Food and Drug Administration
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Silver Spring, MD 20993-0002

EC-WEB CO., LTD.
% Dr. Ke-Min Jen
Official Correspondent
4F., NO. 89, Taiyuan Road, Datong Dist.
Taipei City, 103 Taiwan
REPUBLIC OF CHINA

February 23, 2016

Re: K152034
Trade/Device Name: FS-PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 14, 2016
Received: January 20, 2016

Dear Dr. Jen:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR 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/MedicalDevices/Safety/ReportaProblem/default.htm> 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned above the typed name and title.

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152034

Device Name

FS-PACS

Indications for Use (Describe)

The EC-WEB FS-PACS is intended for the manipulation, management, and display of medical images. It can manage and display images from different modalities and interfaces and can distribute those images to various workstation, image storage and printing devices using DICOM or similar standards. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using cleared monitors intended for mammography display. Typical users of this system are trained medical professionals, including physicians, nurses, technicians and computer system professionals.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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B. Administrative Information

B.1 510(K) Summary of Safety and Effectiveness

(Per 21 CFR 807.92)

Type of 510(k) Submission	Traditional
Basis for the submission	A New Device (There is no prior submission for the subject derive.)
510(k) Submitter	EC-WEB CO., LTD. 4F., No.89, Taiyuan Rd., Datong Dist., Taipei City 103, Taiwan (R.O.C.) Telephone: +886-2-2550-4790 Fax: +886-2-2559-8682 Web: www.e-web.com.tw
Official Correspondent	Dr. Jen, Ke-Min TEL: +886-3-5208829 FAX: +886-3-5209783 Email: ceirs.jen@msa.hinet.net
Preference for Continued Confidentiality (21 CFR 807.95)	510(k) Summary
Date Prepared	January 14, 2016
Proprietary (Trade) Name	FS-PACS
Common Name of the Proposed Device	Picture Archiving and Communications System
Classification Name	Picture Archiving and Communications System
Regulation Number	21 CFR 892.2050
Class	II
Panel	Radiology
Product Code	LLZ
Predicate Device	DATAKOM TECHNOLOGY CORP DATAKOM DC-PACS K083182



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- **Indications For Use::**

The EC-WEB FS-PACS is intended for the manipulation, management, and display of medical images. It can manage and display images from different modalities and interfaces and can distribute those images to various workstations, image storage and printing devices using DICOM or similar standards. *Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using cleared monitors intended for mammography display.* Typical users of this system are trained medical professionals, including physicians, nurses, technicians and computer system professionals.

- **Device Description:**

The EC-WEB FS-PACS system is based on DICOM standard application. The main function of FS-PACS is about medical image management within a PACS environment. It's including image archival, retrieval and distribution of medical images.

FS-PACS can support the following modality: CR, ES, NM, RF, US, CT, MG, OT, RT, XA, DX, MR, PT, SC, VR, IO, SR. There is no 3D image manipulation functions. FS-PACS provides the following measurement tools: 2-point distance, 3-point angles, ellipse area, and square area. FS-PACS can support the iOS device (i.e., iPad and iPhone). Images reviewed on the mobile device are not intended for diagnostic use. FS-PACS does not include any type of imaging hardware. It does not provide any masking or image filtering functions.

- **Technological Characteristics:**

FS-PACS has multiple software components and has no imaging hardware. The FS-PACS is a software server application and 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.



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- **Comparison Table**

Devices	Predicate device	Subject device
Proprietary Name	DATAKOM DC PACS	FS-PACS
510(k) No.	K083182	TBA
Manufacturer	DATAKOM Technology Corp.	EC-WEB CO., LTD.
Same Characteristics		
Classification Name	Picture Archiving and Communications System	Same
Regulation Number	21 CFR 892.2050	Same
Product Code	LLZ	Same
Indications for Use	<p>The DATAKOM™ DC-PACS is intended for the manipulation, management, and display of medical images. It can manage and display images from different modalities and interfaces and can distribute those images to various workstation, image storage and printing devices using DICOM or similar standards. Typical users of this system are trained medical professionals, including physicians, nurses, technicians and computer system professionals.</p>	<p>The EC-WEB FS-PACS is intended for the manipulation, management, and display of medical images. It can manage and display images from different modalities and interfaces and can distribute those images to various workstation, image storage and printing devices using DICOM or similar standards. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using cleared monitors intended for</p>



		mammography display. Typical users of this system are trained medical professionals, including physicians, nurses, technicians and computer system professionals.
Networking Communications Protocol	DICOM 3.0	Same
DICOM C-Store Service	DICOM Workstation can use this function to send the DICOM file to PACS	Same
DICOM C-Echo Service	DICOM Workstation can use this function to verify the DICOM service of PACS	Same
DICOM Query/Retrieve Service	PACS Viewer can use this function to search with PACS, and view the DICOM image from PACS.	Same
DICOM C-Find Service	DICOM Workstation can use this function to get patient information from PACS.	Same
DICOM Image backup system	Backup DICOM images and database	Same
Different Characteristics		
DICOM Multi-port C-Store Service	None	PACS can set multi-port to retrieve DICOM images from DICOM Workstations in hospital.
Customize Paper Print	None	PACS Viewer can use this function to customize the print layout.



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Dental Template	None	PACS has dental template to view the intraoral DICOM image. This dental template can be customized by user.
Client Viewer Login User Permission	None	PACS has permission to control every accounts and limit their functions for user
Capture DICOM image during recording	None	Capture workstation can capture image during recording
Convert document file to DICOM image	None	Gateway can convert document file or send to PACS.
Convert digital image to DICOM image	None	Gateway can convert digital image to DICOM image and send to PACS with mobile device.
Access DICOM image from Internet	PACS provides Web-Viewer to access DICOM image from Internet	Web-Viewer can invite and synchronize exam images with other online user.
Parse the DICOM SR (Structure Report) file	None	FS-Workstation can parse the DICOM SR (Structure Report) file and insert the measurement value to customize report by user.
Monitoring FS-PACS program	None	A monitor program to get status from all of FS-PACS program, when one of FS-PACS program gets error, it will restart that program automatically.



- **Substantial Equivalence (SE) Discussion**

A claim of substantial equivalence is made to DATACOM DC-PACS (K083182). Both of them have the similar indications for use, the same working principle and technologies. The extra statement about the mammographic images for the subject device provides more safety consideration than the predicate device. The other differences are due to the feature design aspects, not related to the safety and effectiveness aspects. This submission contains the results of software validation that the risks analysis and the potential hazards have been classified as Moderate Level of Concern. Thus they are substantially equivalent.

- **Synopsis of Test Methods and Results**

Non-clinical data are employed upon submission of this 510(k) premarket notification according to the FDA guidance document, Guidance for Industry: Guidance for the Submission of Premarket Notifications for Medical Image Management Devices. Document issued on: July 27, 2000.

- **Conclusion**

The conclusions drawn from the non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device identified in the submission. Thus the subject device is substantially equivalent to the predicate devices.