合華科技股份有限公司
DATACOM TECHNOLOGY CORP.
6F,NO.69-3,SEC.2,CHUNG CHENG E.RD.,
TAM SHUI,TAIPEI,TAIWAN,R.O.C.
TEL:886-2-28094611 FAX:886-2-28094681
E-MAIL:Kenneth@datacom.com.tw http://www.datacom.com.tw

MAR 4 2009

K083182

2. ADMINISTRATIVE INFORMATION

FDA CDRH DMC

OCT 28 2008

Received

2.1 510(k) Summary of Safety and Effectiveness

(Per 21 CFR 807.92)

General Information Establishment

- Manufacturer: **DATACOM Technology Corp.**
- Address: 6F, No.69-3, Sec.2, Chung Cheng E. Rd., Tam Shui, Taipei, 25170, Taiwan, ROC
- Owner Number: **10026153**
- Contact Person: Dr. Jen, Ke-Min E-mail: ceirs.jen@msa.hint.net
  (official correspondent) 886-3-5208829 (Tel); 886-3-5209783 (Fax)
  Address: No.58, Fu Chiun Street, Hsin Chu City, 30067, Taiwan, ROC
- Date Prepared: October 24, 2008

Device Information

- **Proprietary Name:** DATACOM™ DC-PACS
- **Classification Name:** SYSTEM, IMAGE PROCESSING, RADIOLOGICAL, Class II
- **Regulation Number:** 892.2050
- **Product Code:** LLZ

Safety and Effectiveness Information

- **Predicate Device:**

  Claim of Substantial Equivalence (SE) is made to Taiwan Electronics Data Processing Corporation Smart PACS **(K022710)**

- **Device Description:**

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

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- **Intended Use:**

  The DATACOM™ 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.

- **Technological Characteristics**

  The DATACOM™ DC-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.

- **Substantial Equivalence (SE)**

  A claim of substantial equivalence is made to Smart PACS **(K022710).** Both of them have the same working principle and technologies. The differences are due to the feature design aspects, not relating to the safety or effectiveness aspects. Besides, the submission contains the results of software validation that the risks analysis and the potential hazards have been classified Minor. Thus they are substantially equivalent.

Dr. Jen, Ke-Min
official correspondent for
DATACOM Technology Corp.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 4 2009

DATACOM Technology Corp.
% Dr. Jen, Ke-Min
Official Correspondent
ROC Chinese-European Industrial Research Society
No. 58, Fu Chiun Street
Hsin Chu City , 30067, ROC
TAIWAN

Re: K083182
Trade/Device Name: DATACOM™ DC-PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 15, 2009
Received: January 21, 2009

Dear Dr. Jen, Ke-Min:

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 os 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 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Manufactures, 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.suppot/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

台華科技股份有限公司
DATACOM TECHNOLOGY CORP.
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2.2 FDA Indication for Use Form :

Indications for Use

510(k) Number: K083182

Device Name: DATACOM Technology Corp.

DATACOM™ DC-PACS

Indications for Use :

- The DATACOM™ 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.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K083182