K072960
Page 1 of 3

510(k) SUMMARY

CDP Ltd.'s CDP 5000

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

CDP Ltd.
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NOV 0 8 2007

Contact Person: Doron David

Date Prepared: June 5, 2007

Name of Device and Name/Address of Sponsor

CDP 5000, Media & Distribution Center, DiagNET

23 Efal Street
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P.O. Box 3325
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Common or Usual Name

Picture Archiving Communications System (PACS)

Classification Name

Image Processing system
Product Code LLZ – 21 CFR 892.2050

Predicate Device

eFilm Medical Inc. **eFilm Workstation with Modules**, K020995, for image viewing and manipulation.

Intended Use

The **CDP 5000** is a software application that is used for receiving, managing, archiving, distributing and recording medical images onto portable digital media (including but not limited to Compact Disk and DVD).

The **CDP 5000** receives digital images and data from various sources (including but not limited to CT, MR, US, NM, XA, RF, computed and direct radiographic devices, secondary capture devices, scanners, imaging gateways or imaging sources).

Users of **CDP 5000** can perform the following tasks:

- Query and retrieve images from the CDP 5000 Archive, using any third party workstation capable of performing DICOM query/retrieve functions.
- Use DIAGNET network viewer to search, retrieve and manipulate patient images.
- Create DICOM compliant portable media (i.e. CD-R) containing: original DICOM images as sent by imaging modality and the DIAGNET viewer application.

Tasks that users of DIAGNET may perform include, but are not limited to: navigation; adjustment of window width and level; image stacking; measurements; inversion; zoom; magnification; rotation, Linked navigation, MPR (Multi-Planar Reformatting).

Typical users of the **CDP 5000** and **DIAGNET** are trained medical professionals, including but not limited to radiologists, clinicians, technologist, and others.

Technological Characteristics and Substantial Equivalence

SUMMARY OF TECHNICAL DEVICE DESCRIPTION AND SPECIFICATIONS

The **CDP 5000 Ensemble** is a software application that is used for receiving, managing, archiving, distributing and recording medical images onto portable digital media (including but not limited to Compact Disk and DVD). The DIAGNET Viewer software, which is copied to every CD produced, runs automatically when the CD is placed in any Windows-based PC; it allows the examinee to view, manipulate, perform measurements on, and post-process the received images. The images can then be saved, copied, and/or sent to a file, emailed, or included in a report in process.

The **CDP 5000** is substantially equivalent to the currently marketed eFilm Medical Inc.'s **eFilm Workstation with Modules,** which was referenced above. The **CDP 5000** and its predicate device are both picture archiving communications systems. Thus, the **CDP 5000** raises no new issues of safety or effectiveness.

Performance Data

Performance tests were performed by CDP Ltd. on the **CDP 5000**. In all instances, the **CDP 5000** functioned as intended and the results observed were as expected.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 8 2007

CPD, Ltd.
% Mr. Harry van Vugt
Official Correspondent
KEMA Quality B.V.
4377 County Line Road
CHALFONT PA 18914

Re: K072960
Trade/Device Name: CPD 5000/MEDIA & Distribution Center and Diagnet Client
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 15, 2007
Received: October 19, 2007

Dear Mr. van Vugt:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(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 Biometric's (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,

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

Indication for Use

510(k) Number (if known): K072960

Device Name: CDP 5000/MEDIA & DISTRIBUTION CENTER and DIAGNET CLIENT

Indication for Use:

The **CDP 5000** is a software application that is used for receiving, managing, archiving, distributing and recording medical images onto portable digital media (including but not limited to Compact Disk and DVD).

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Prescription Use X
(Part 21 CFR 801 Subpart D)

Over-the-Counter Use _____
(21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072960