510(k) Summary
ALZ, Inc.
ALZ Web PACS (Version 1.0)

JUN 11 2008

1. Company Name and Address

ALZ, Inc.
18207 Cedar Island Blvd.
Brownstown , MI 48174

Contact: Nasser Al Zawawi
Phone: 313-887-9345
Fax: 888-467-1853

2. Device Name

Proprietary Name:	ALZ Web PACS (Version 1.0)
Common/Usual Name:	PACS
Device	System, image processing, radiological
Classification Name:	Picture archiving and communication system
Product Code	LLZ
21 CFR Regulation	892.2050

3. Predicate Device

- eFILM Workstation with Modules, K020995, Merge eMED, Inc.
- UniPACS, K023476, Universal PACS, Inc.

4. Device Description

The ALZ Web PACS (Version 1.0) is designed for the management, viewing, and processing of DICOM images. The ALZ Web PACS consists of the ALZ Web PACS software application installed on a server and the ALZ Web PACS viewer running on client computers connecting to the server via the HTTPS protocol.

5. INTENDED USE

The ALZ Web PACS (Version 1.0) is an imaging software system intended to be used by trained healthcare professionals. The ALZ Web PACS is used with general purpose computing hardware to acquire, transmit, store, view, and process DICOM images.

This device is not intended for mammography

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Both the proposed and predicate devices are software devices used with general purpose computing hardware to acquire, transmit, store, view, and process medical images. Both the proposed and predicate devices consist of a software application that is installed on a server that communicates with client PCs that connect via a TCP/IP (HTTPS for ALZ client/application server communication and DICOM Protocol for communication between the ALZ application server and other DICOM compliant devices). Basic file acquisition, storage, and sending functions, as well as image viewing and manipulation are shared by both the proposed and predicate software programs.

7. PERFORMANCE TESTING

The ALZ Web PACS was tested to verify that the device meets prospectively defined design and performance specifications. The results of the testing confirmed that the ALZ Web PACS performed as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2008

ALZ, Inc.
% Ms. Cindy Nolte
Senior Regulatory Consultant
Medical Device Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

Re: K081304
Trade/Device Name: ALZ Web PACS (Version 1.0)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 7, 2008
Received: May 8, 2008

Dear Ms. Nolte:

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

Indications for Use

510(k) Number: K081304

Device Name: ALZ Web PACS (Version 1.0)

Indications For Use:

ALZ Web PACS (Version 1.0) is an imaging software system intended to be used by trained healthcare professionals. ALZ Web PACS is used with general purpose computing hardware to acquire, transmit, store, view, and process DICOM images.

This device is not intended for mammography.

Prescription Use ___X___ 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 NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081304