5 510(k) Summary

As required by section 807.92(c)

DEC - 3 2010

510(k) owner's name:	Fimreite Software AS
Address:	Torggata 26, 3181 Horten, Norway
Phone:	(47) 93 21 56 27
Contact person:	Svein Fimreite
Date of preparation:	29 October 2010
Name of Device	PaCentric Web
Trade Name:	PaCentric Web
Common Name:	Picture Archiving and Communications Systems and Workstation
Classification Name:	21 CFR 892.2050 System, Image Processing, Radiological
Predicate Device:	K062488 iQ-System PACS
Device Description:	PaCentric Web is an Internet application for read-only review of external image deliveries. PaCentric Web facilitates the display and/or transfer of clinical DICOM images and reports to a Web browser. PaCentric is ensuring secure and time-limited access to clinical data. The receiver will only have access to the relevant data for a particular delivery. Using PaCentric, patient data can be delivered to a specific recipient anywhere in the world. PaCentric Web gives a qualified user read-only access to an image delivery. Access is given with a key and password, which must be provided by the Sender. PaCentric Web features commonly used tools and features found on DICOM workstations: • Preview image icons from which the user may select images to review in full size • Measurements: Distance, Area, Volume, Angle and ratios. Measurement calibration based on information provided by the relevant DICOM tag. The measurements are performed by having the user select a caliper and marking end points by clicking with a mouse button. The results are being displayed and updated in a results area on the screen. • Horizontal and Vertical invert, i.e. flipping the image sideways or upside-down. • Color maps. A pixel consists of three sets of values from 0 to 255 that together constitute a color or a gray level. Technically, these RGB values are reduced according to desired color hue. A grayscale image therefore will not lose any details in the image for higher or lower values. This function is mostly used for MONOCHROME1 and MONOCHROME2 images. • Window-leveling and Brightness control. These Attributes is only used for Images with Photometric Interpretation (0028,0004) values of MONOCHROME1 and MONOCHROME2. They have no meaning for other Images. When working with DICOM images, the user has the ability to make changes to the displayed images, on a global level, by manipulating the Window Level. Tonal changes to specific areas of an image. Window Center DICOM TAG 0028,1050 and Window Width DICOM TAG 0028,1051 specify a linear conversion from stored pixel values (after any Modality LUT or Rescale Slope and Intercept specified in the IOD have been applied) to

	values to be displayed. Window Center contains the input value that is the center of the window. Window Width contains the width of the window. Note: The terms "window center" and "window width" are not consistently used in practice, nor were they defined in previous versions of the standard. The definitions here are presented for the purpose of defining consistent meanings for identity and threshold transformations while preserving the common practice of using integral values for center and width. • Zoom – Image is downloaded in its original size, but the height and width definition can be adjusted and will therefore function as zoom. • Language selection. Default language is based on current location derived from the IP address of the viewer. • Simple printable report with preview and selectable fields: Display of patient demographics: Sex, age, date of examination, nationality, operator, weight, referring physician, height, performing physician, body surface area (BSA), location, BP, Sender address, Description, Diagnosis, Comments, Images, selectable signature lines • Ability to display up to eight independent image areas at the same time
Intended Users:	Intended users PaCentric Web include radiologists, specialists including cardiologists, surgeons, chiropractors, dentists and other trained medical professionals who have a need for reviewing clinical data acquired at some other geographic location.
Intended Use:	PaCentric Web is a software device intended for viewing of images acquired from CT, MR, CR, DR, US and other DICOM compliant medical imaging systems when installed on suitable commercial standard hardware. Images and data can be captured, stored, communicated, processed, and displayed within the system and or across computer networks at distributed locations. The device is not intended for clinical viewing of mammography images.
Technology:	PaCentric Web use the same functional scientific technology as its predicate devices including a transfer protocol based on Query/Retrieve within the DICOM standard. In addition, PaCentric uses secure transfer protocols with VeriSign Class 3 Extended Validation SSL CA HTTP with Privacy TLS 1.0, AES with 128 bit encryption (High); RSA with 1024 bit exchange for internet communication.
Test Summary:	PaCentric Web complies with the voluntary standards as detailed in Section 9. The following quality assurance measures were applied to the development: • Risk Analysis • Requirements Reviews • Design Reviews • Testing on unit level (Module verification) • Integration testing (System verification) • Final acceptance testing (Validation) • Performance testing
Conclusion:	Fimreite Software AS considers features of PaCentric Web substantially equivalent to those of the predicate device, but believes that PaCentric should be considered a device with Moderate Level of Concern.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Svein Fimreite
Managing Director
Fimreite Software AS
Torggata 26, Horten, 3181
NORWAY

DEC - 3 2010

Re: K100837
Trade/Device Name: PaCentric Web
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 28, 2010
Received: November 9, 2010

Dear Mr. Fimreite:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4 Indications for Use Statement

DEC - 3 2010

510(k) Number: K100837

Device Name: PaCentric Web

Indications for Use:

PaCentric is a software only device intended for viewing of images acquired from CT, MR, CR, DR, US and other DICOM compliant medical imaging systems when installed on suitable commercial hardware. Images and data can be captured, stored, communicated, processed, and displayed within the system and or across computer networks at distributed locations. The device is not intended for clinical viewing of mammography images.

Prescription Use **YES** (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use **NO**

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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