



Food and Drug Administration
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DICOM Grid, Inc.
% Ms. Calley Herzog
Senior Consultant
Biologics Consulting Group, Inc.
400 N. Washington Street, Suite 100
ALEXANDRIA VA 22314

January 25, 2016

Re: K152977
Trade/Device Name: DG PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 4, 2016
Received: January 6, 2016

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 "Robert Ochs, Ph.D." The signature is written in a cursive style and is positioned over a large, faint, semi-transparent watermark of the FDA logo.

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)

K152977

Device Name

DG PACS

Indications for Use (Describe)

DG PACS software is intended for use as a primary diagnostic and analysis tool for diagnostic images for hospitals, imaging centers, radiologists, reading practices and any user who requires and is granted access to patient image, demographic and report information.

DG Viewer, a component of DG PACS, displays and manages diagnostic quality DICOM images.

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.

Not intended for diagnostic use on mobile devices.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) Summary

Application Version: 3.0

Prepared: Oct 10, 2015

Submission Number: K152977

This 510(k) summary of safety and effectiveness information for DG PACS is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:

Oct 10, 2015

Submitter Information 21 CFR 807.92(a)(1):

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510(k) Correspondent Information 21 CFR 807.92(a)(1):

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Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2):

Trade Name: DG PACS
Common Name: Picture, archive and communications system
Classification Name: System, Image Processing, Radiological
Product Code: LLZ

Predicate Device 21 CFR 807.92(a)(3):

Device Classification Name	<u>System, Image Processing, Radiological</u>
510(K) Number	K120995
Device Name	ERAD PACS/ERAD RIS/PACS/ERAD EPVLITE VIEWER SOFTWARE PRODUCT
Original Applicant	ERAD, INC. 23 Griswold Lane Winsted, CT 06098
Original Contact	Jillian M Reed



510(k) Summary

Application Version: 3.0

Prepared: Oct 10, 2015

Submission Number: K152977

Regulation Number	<u>892.2050</u>
Classification Product Code	<u>LLZ</u>
Date Received	04/02/2012
Decision Date	12/03/2012
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Radiology
510k Review Panel	Radiology
Summary	<u>Summary</u>
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

Device Description 21 CFR 807 92(a)(4):

DG PACS is considered a 'Continuous Use' device. This device is compliant with HIPAA/HITECH, Safe Harbor, and 21 CFR Part 11 regulations regarding patient privacy (such as restricting access to particular studies, logging access to data), data integrity, patient safety and best software development and validation practices.

Indications for Use 21 CFR 807 92(a)(5):

DG PACS software is intended for use as a primary diagnostic and analysis tool for diagnostic images for hospitals, imaging centers, radiologists, reading practices and any user who requires and is granted access to patient image, demographic and report information.

DG Viewer, a component of DG PACS, displays and manages diagnostic quality DICOM images.

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Not intended for diagnostic use on mobile devices.

Technological Characteristics 21 CFR 807 92(a)(6):

DG PACS is a software application that handles and manipulates digital medical images for diagnostic, clinical, research or education purposes. The device does not contact the patient, nor does it control any life sustaining devices. A physician interprets images and information on DG PACS.

In general, a Picture Archiving and Communication System (PACS) is a medical imaging technology that provides storage of, and convenient access to, images from multiple modalities. Electronic images and reports are transmitted digitally via PACS: this eliminates the need to manually file, retrieve, or transport film jackets. The universal format for PACS image storage and transfer is the Digital Imaging and Communications in Medicine (DICOM 3.x). Non-image data, such as scanned documents or dictated reports, may be incorporated using consumer industry standard formats like Portable Document Format (PDF) once



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encapsulated in DICOM.

Utilization of Standards: Digital Imaging and Communications in Medicine (DICOM)
Joint Photographic Experts Group (JPEG)
Society of Motion Picture and Television Engineers (SMPTE)

Substantial Equivalence 21 CFR 807.87(f)

The new device (DG PACS) and predicate device (eRADS RIS / PACS) are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. The new device does not raise any new potential safety risks and is equivalent in performance to the existing legally marketed devices. Both systems have been developed to replace traditional film handling in radiology. The two devices are substantially equivalent in the areas of design, architecture, general function, application, and intended use. A full comparison of features, equivalency and risk analysis may be found in the Substantial Equivalency Section of the full 510(k) submission.

Nonclinical Testing 21 CFR 807.87(f)

The complete DG PACS system access specifications, configuration and functional specifications have been assessed, tested and passed all in-house testing criteria. The test plan was designed to evaluate all input functions, output functions, and actions performed by DG PACS software in each operational mode and followed the process documented in the test plan. The System Access Test Plan and Report specifically evaluated data integrity and PHI confidentiality, and similarly passed in-house testing and evaluation. Supporting software and IT infrastructure went through a congruent validation and verification process including risk assessment, requirements specification, testing planning and execution.

Nonclinical testing results are provided in the 510(k) and more detailed reports are included in the Annex. Verification and validation testing indicated that as required by the risk analysis, designated trained individuals performed all validation activities and that the results demonstrated that the predetermined acceptance criteria were met. Devices installed or implemented by DICOM Grid, Inc include integration and installation validation testing against defined user acceptance criteria, the results of which are disclosed to the client prior to release.

The software documentation was provided at a moderate level of concern following the FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". DG PACS complies with voluntary standards as detailed in this premarket notification submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Usability Analysis
- Testing on unit level (Verification)
- Integration testing (Verification)
- Performance testing (Verification)
- Regression testing (Verification)
- System testing (Verification)



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- Simulated use testing (Validation)

Additionally, DG PACS quality testing was conducted based upon industry QC monitor benchmarks developed by Society of Motion Picture & Television Engineers (SMPTE), American Association of Physicists in Medicine (AAPM), and David Clunie's pixel spacing test images for DICOM. All image display quality validation was successful, and can be reviewed in detail in the software testing and validation portion of the 510(k) or live at dicomgrid.com/compliance/qc.

Conclusion 21 CFR 807 92(b)(1):

The 510(k) Pre-Market Notification for DG PACS contains adequate information, data, and nonclinical test results to enable FDA-CDRH to determine substantial equivalence to the predicate device, in this case eRADS RIS / PACS. The subject device will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The subject and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. The modification to the subject device does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices. Nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the predicate device. Therefore, DG PACS is substantially equivalent to the predicate devices.