5. CardioPACS 510(k) Summary

JUL 5 2012

The following safety and effectiveness summary has been prepared pursuant to 21CFR807.87 and 21 CFR 807.92 (for 510(k) summaries).

Submitter Information

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Contact Person: Chris Pearce
Date prepared: Dec 29th 2011

Device name and Classification

Trade name:	HealthView CardioPACS (version 6.0)
Common name:	Picture Archiving and Communications System (PACS)
Classification Name:	System, Image Processing, Radiological
Classification number:	21CFR Part 892.2050
Device Class:	Class II
Product Code:	LLZ (Radiology Panel)

Substantial Equivalence

The HealthView CardioPACS (version 6.0) device, addressed in this premarket notification, is substantially equivalent to both of the following commercially available devices:

510(k) #	Trade Name	Manufacturer
K041581	ComPACS	MEDIMATIC, Genova, Italy
K102150	*syngo* Dynamics (version 9.0)	Siemens Medical Solutions USA Inc. Ann Arbor, MI 48108

Device description

HealthView CardioPACS (version 6.0), herein after referred to as CardioPACS, is a Picture Archive Communications System. It is a "software only" medical device, to be installed on a server and workstation(s) that meet the minimum hardware requirements noted in the documentation. The hardware itself is not considered a medical device and is not part of this 510(k) submission. The device provides a trained user with the ability to find, retrieve, view,

edit and manipulate images on a workstation, to assist in the diagnosis and treatment planning of patients. The device does not contact the patient and does not control any life sustaining devices.

Intended Use

CardioPACS is a software device intended to be used by medical professionals, for storage, review, query/ retrieve, analysis and post processing of DICOM medical images as may be generated by echocardiography, radiology and other modalities. The device may be used as a stand-alone product, or in a networked system.

CardioPACS is not intended to be used for reading of mammography images.

Technological characteristics of the device

CardioPACS is a software-only DICOM-compliant device that can be used on multiple hardware platforms (provided that the minimum hardware requirements are met) that allows viewing, editing, measuring and other digital image processing. This device is used by trained and qualified professionals who have ample opportunity for competent human intervention in interpreting the images and information presented to them. These technological characteristics are the same as those in the predicate devices, in terms of hardware needs, operating system requirements, overall functional characteristics, storage methodology, image generation and DICOM standards compliance. This device does not physically come in contact with a patient, nor does it control any life-sustaining devices.

Performance Test Data

Every identified requirement has been tested and confirmed to be performing as expected (see Section 16, and provided screen shots of test files). Additionally, performance of the device has been substantiated in multiple ways: i) verifying accuracy of measurement tools using other cleared devices, ii) verifying the speed of performance in a simulated network environment, iii) validating the retrieval speed at a validation site, and iv) validating tools accuracy at a validation site.

General Safety and Effectiveness Concerns

CardioPACS has been tested to confirm compliance with voluntary standard DICOM version 3.0. Risk management is ensured by use of the ISO14971 (2007) standard, which has been used to identify and mitigate potential hazards. These potential hazards are also individually confirmed to be controlled via verification and validation testing, and any necessary cautions and warnings are included in user documentation.
Images and text created or modified on this device are evaluated by medical professionals, thus allowing for intervention in the event of a malfunction.

Lumedx therefore believes this device to be as safe and effective as the predicate devices referenced above; it does not introduce new technology or new indications for use.

Conclusions - Substantial Equivalence

This submission includes the results of a hazard analysis, and shows that the potential hazards have been controlled. The Level of Concern of the device has been demonstrated to be "Moderate". All verification and validation testing has successfully concluded. The 510(k) pre-market notification for the HealthView CardioPACS (version 6.0) contains adequate information to show substantial equivalence to the listed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Chris Pearce
Director, Regulatory Affairs
LUMEDX Corporation
110 – 110th Avenue NE, Suite 475
BELLEVUE WA 98004

JUL 5 2012

Re: K120514
Trade/Device Name: CardioPACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 11, 2012
Received: June 14, 2012

Dear Mr. Pearce:

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,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K120514
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4. Indications for Use Statement

CardioPACS is a software device intended to be used by medical professionals, for storage, review, query/ retrieve, analysis and post processing of DICOM medical images as may be generated by echocardiography, radiology and other modalities. The device may be used as a stand-alone product, or in a networked system.

CardioPACS is not intended to be used for reading of mammography images.

Prescription Use ___X___ AND/OR
(Part 21 CFR 801 Subpart D)

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)
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(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K120514