K123466

5. HealthView ECG Manager 510(k) Summary

DEC 2 0 2012

The following safety and effectiveness summary has been prepared pursuant to 21 CFR 807.87 and 21 CFR 807.92 (for 510(k) summaries).

Submitter Information

LUMEDX
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Contact Person: Chris Pearce
Date prepared: Nov 5th 2012

Device name and Classification

Trade name: HealthView ECG Manager (version 1.0)

Common name: ECG Management System
Classification Name: Programmable Diagnostic Computer
Classification number: 21 CFR Part 870.1425
Device Class: Class II
Product Code: DQK (Cardiology Panel)

Substantial Equivalence

The HealthView ECG Manager (version 1.0) device, addressed in this premarket notification, is substantially equivalent to both of the following commercially available devices:

510(k) #	Trade Name	Manufacturer
K052883	Cardio Server	Epiphany
K083639	MUSE	GE Healthcare

Device description

HealthView ECG Manager (version 1.0), herein after referred to as ECG Manager, is a Programmable Diagnostic Computer 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 and integrate ECGs into a single patient record, 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

The HealthView ECG Manager is a computer system, used within a clinical network, which is intended to be used by trained professionals. It provides the ability to retrieve, store, edit, send and print ECGs and related digitized clinical documents through the use of on-screen measurement and editing tools. The system receives files (such as ECG, stress, or Holter) from any compatible device, displaying such data to the clinician for analysis and review.

The product does not modify the original ECG waveform and does not provide an automated ECG analysis.

Technological characteristics of the device

ECG Manager is a software-only device that can be used on multiple hardware platforms (provided that the minimum hardware requirements are met) that allows acquiring, archiving, viewing, and editing. This device is used by trained and qualified professionals who have ample opportunity for competent human intervention in interpreting the waveforms 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, and waveform generation. 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.

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General Safety and Effectiveness Concerns

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.

Data 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 ECG Manager (version 1.0) 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 Center – WO66-G609
Silver Spring, MD 20993-0002

DEC 2 0 2012

LUMEDX.
c/o Mr. Chris Pearce
Director, Regulatory Affairs
110, 110th Ave NE
Bellevue, WA 98004

Re: K123466
Trade/Device Name: HealthView ECG Manager
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: November 8, 2012
Received: November 9, 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. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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4. Indications for Use Statement

The HealthView ECG Manager is a computer system, used within a clinical network, which is intended to be used by trained professionals. It provides the ability to retrieve, store, edit, send and print ECGs and related digitized clinical documents through the use of on-screen measurement and editing tools. The system receives files (such as ECG, stress, or Holter) from any compatible device, displaying such data to the clinician for analysis and review.

The product does not modify the original ECG waveform and does not provide an automated ECG analysis.

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 Cardiovascular Devices

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