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

Visual Medica
% Ms. Melissa Llabrés Grau
Official Correspondent
Ecuador 1465 1ºD, CP: 1425
Ciudad Autonoma de Buenos Aires
ARGENTINA

January 16, 2015

Re: K141561
Trade/Device Name: VM PACS with VM Medical Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 22, 2014
Received: December 29, 2014

Dear Ms. Grau:

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,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141561

Device Name
VM PACS with VM Medical Workstation

Indications for Use *(Describe)*
VM PACS is designed to Store Medical Dicom Images and leave them available to be used for diagnostics or transferred to other Dicom devices.

VM PACS is not meant to create or modify DICOM images. VM PACS store the images and the Data Set send by an DICOM compatible image diagnostic equipment and store them making them available to be access by a workstation or viewer, or been transfer to another Dicom Compatible device.

VM PACS does not modify the images store in it.

User Graphic interface VM Medical Workstation is a complete Workstation which provides diagnostic tools for image diagnose, for CT, MR, PT, CR, DX, NM, MG, XA, RF, SC, US and ES, as zoom, Window & Level variation and presets, measurements and a complete set of diagnostics tools and includes a report tool for the studies.

Lossy compressed mammographic images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA cleared display that meets technical specifications reviewed and accepted by FDA.

VM Clinical Viewer is the web access interface of VM PACS, which allows integration with any Operating System, brings to the institution the capacity to access the images remotely.

VM Clinical Viewer allows the specialist consultation and the communication between radiologists and referring physicians. The system enables authorized external users to have access to specific patient studies, is not intended for diagnostic purposes when used 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.

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1 510(K) SUMMARY

15 Jan, 2015

New Device

Company Name: Visual Medica

DUNS Number: 976989421

Phone Number: +5411 4825 4855

Address: Ecuador 1465 1°D, CP: 1425, Ciudad Autónoma de Buenos Aires, Argentina

Contact Information

Name: Melissa Llabrés Grau

email: melissa@visualmedica.com

Contact Direct Number: +549 11 5883 0355

Product: VM PACS with Medical Workstation

Product: Picture Archiving and Communication System (PACS)

Commercial Name: VM PACS with VM Medical Workstation

Classification: 892.2050 (Class II)

Product Code: LLZ

PREDICATE DEVICE:

510 (k) Number	*Model Name*	*Manufacturer*
K123174	CENTRICITY PACS-IW WITH UNIVERSAL VIEWER	GE HEALTHCARE

1.1 Device Description

VM PACS WITH VM MEDICAL WORKSTATION

VM PACS with VM Medical Workstation is a software composed by a Picture Archiving and Communication System able to receive, transfer and display Dicom Images acquired and send by imaging devices such as CT, MR, CR, DX, MG, US, NM, PET, and other devices, along with a Graphic interface used to configure the PACS and diagnose Medical Images Stored in it.

1.1.1 VM PACS

VM PACS is an affordable and scalable Picture Archiving and Communication System designed to optimize imaging workflow and simplify image management

Use a powerful database engine as client server data. The system architecture scalable, allowing to add storage media according to the volume of studies intended to store and be access online. This gives the possibility to increase gradually the investment in hardware storage as needed.

All Image Storage and communications are according to the Dicom Standard. A configuration interface allows the system administrator to set the Application Entity Title (AE-TITLE) and listening port for the Dicom Communications with other devices

To protect the studies PACS has a full-featured fully automatic and programmable backup instance.

VM PACS is capable to send query and retrieve studies from other Dicom Applications using the DICOM standard. For Monitoring the Dicom traffic, incorporating a tool which shows all the DICOM transfers in a lapse of time, also VM PACS can be set to auto send studies to other Dicom Application Entities (AEs), depending on the modality, the description, the patient, or any other Dicom Tag selected and also can send all the previous studies from the same patient to a target Dicom AE.

1.1.2 VM Medical Workstation

VM Medical Workstation provides all the necessary tools needed for image diagnosis.
VM Medical WS allows the user to visualize; report and print images and studies, whit a complete set of tools designed for diagnose medical images.
VM Medical Workstation includes a report module to archive the diagnostic results, linked to the informed study.

VM Medical WS allows the authorized user to burn studies in a CD/DVD along with the study have an autorun software with diagnostic Dicom tools. If the study has a report, this report is attached to the CD/DVD in a PDF format.

The software also include an Advance Printing tool which allows the user to perform a personalized layout, changing window & Level, zoom, and pan to one or all images in the layout.

1.1.3 VM Clinical Viewer

VM Clinical Viewer is the diagnostic web access interface of VM PACS, which allows integration with any Operating System, and allows the institution to access the images remotely.

VM Clinical Viewer improves the specialist consultation and the communication between radiologists and referring physicians from any location in the world. The system enables authorized external users to have access to specific patient studies.

VM Clinical Viewer is not intended to be use with diagnostics proposes in mobile devices.

1.2 Indications for use:

VM PACS is designed to Store Medical Dicom Images and leave them available to be used for diagnostics or transferred to other Dicom devices.

VM PACS is not meant to create or modify DICOM images. VM PACS store the images and the Data Set send by an DICOM compatible image diagnostic equipment and store them making them available to be access by a workstation or viewer, or been transfer to another Dicom Compatible device.

VM PACS does not modify the images store in it.

User Graphic interface VM Medical Workstation is a complete Workstation which provides diagnostic tools for image diagnose, for CT, MR, PT, CR, DX, NM, MG, XA, RF, SC, US and ES, as zoom, Window & Level variation and presets, measurements and a complete set of diagnostics tools and includes a report tool for the studies.

Lossy compressed mammographic images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA cleared display that meets technical specifications reviewed and accepted by FDA.

VM Clinical Viewer is the web access interface of VM PACS, which allows integration with any Operating System, brings to the institution the capacity to access the images remotely.

VM Clinical Viewer allows the specialist consultation and the communication between radiologists and referring physicians. The system enables authorized external users to have access to specific patient studies, is not intended for diagnostic purposes when used on mobile devices.

1.3 Intended Use

VM PACS with VM Medical Workstation is a software designed to receive, store, distribute, process and display Digital Imaging and Communications in Medicine (DICOM) and non-DICOM information and data throughout a clinical environment. The software performs digital communication and storage of the images and is meant to be administrated by a trained user.

VM Medical Workstation and VM Clinical Viewer are both softwares capable to perform image processing, measurement and other diagnostics tools, it is designed to be used by trained professionals, including but not limited to physicians, nurses and medical technicians.

1.4 Software development

VM PACS with VM Medical WS are designed, developed, tested and validated according to written procedures. These procedures have developing and approving product specifications, coding, testing and field maintenance responsible. The software is used to provide diagnostic-quality images and associated DICOM information to the intended users.

1.5 Safety Information:

The device does not contact the patient, nor does it control any life sustaining devices.

A trained physician, providing ample opportunity for competent human intervention interprets images and information displayed and printed by this software.

1.6 Technological Characteristics

VM PACS is a software designed to be installed in a server with the following minimum requirements, these requirements do not limit any superior hardware which can contain the software.

Connections	Processor	RAM Memory	SO Disk Space	SO	Storage Unit
4 or less	2 Cores	4GB	500 GB	Windows 7/8	2 TB
4 to 8	4 Cores	8GB	500 GB	Windows 7/8	6 TB
8 to 16	8 Cores	16GB	500 GB	Windows Server	12 TB
16 to 32	12 Cores	32GB	500 GB	Windows Server	32 TB
More than 32	16 Cores	32GB	500 GB	Windows Server	40 TB

1.7 Comparison to Predicative Device:

1.7.1 Comparison:

PREDICATE DEVICE: K123174 CENTRICITY PACS (MANUFACTURER: GE)

Centricity PACS (K123174) and VM PACS and VM Medical workstation are designed by DICOM Standards, to store, review; processing, printing film and media interchange of multi-modality images from a variety of diagnosis imaging systems. Both systems give the possibility of multiple users to remotely access the images stored in the main server from compatible hardware on a network. Both systems allow users to manipulation, diagnostic interpretation and post-diagnostic images stored.

As predicative device K123174 Centricity PACS, VM PACS and VM Medical workstation allows the user to export information from the server in different formats including DICOM objects.

Both VM PACS and Centricity PACS provide integration capabilities with other clinical systems as external modality worklist, RIS, HIS, voice recognition and audio report systems.

Therefore this device poses no new issues of safety or effectiveness, and is substantially equivalent to the predicate device.

1.7.2 Differences with Predicative Device:

WORKFLOW

- Audio:

  Predicative Device doesn't have integrated the audio report solution

  "Radiologist will dictate exam through a dictation solution such as embedded VR option or other third-party dictation solution."

  VM PACS integrate the audio report solution.

VISUALIZATION

- Searching Studies

  Predicative Device has Study list display different information.

  Search by referring physician

  VM PACS allows the user to search by Insurance instead of referent physician. This doesn't represent any drawback because all DICOM information is accessible by the Dicom Dump Option in both VM PACS user interfaces.

- Compare button

  For the Study Comparison Predicative device have an automatic tool for placing studies in the screen and synchronize them.

  VM PACS interfaces are able to compare studies by placing them manually on the screen and synchronizing them with synch tool.

1.7.3 Conclusion:

VM PACS and VM Medical workstation are designed by DICOM Standards, allowing easy selection, review; processing and media exchange of multi-modality images from a variety of diagnosis imaging systems.

VM PACS with VM Medial Workstation and predicate devices have been nonclinical tested in the areas of technical characteristics, general function, and application showing Dicom 3 compliance, both softwares also have equivalent indications and intended use. The differences within the subject device do not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices.

Therefore this device poses no new issues of safety or effectiveness, and is substantially equivalent to the predicate device.

1.8 Technology

VM PACS is a software designed to be installed in a server with the following minimum requirements l requirements, these requirements do not limit any superior hardware which can contain the software.

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More than 32	16 Cores	32GB	500 GB	Windows Server	40 TB

2 EXECUTIVE SUMMARY

2.1 VM PACS with VM Medical Workstation Description

VM PACS WITH VM MEDICAL WORKSTATION

VM PACS is Picture Archiving and Communication System created for archiving, manipulating and managing diagnostic medical images, it uses the DICOM protocol to provide the following services:

- Receive images sent by remote stations
- Send images to remote stations
- Print images to a remote printer
- Grayscale Presentation State (GSPS), which specifies the presentation of images as gray scaling, zoom, text and graphical annotations.
- Query remote entities and initiate retrieval from those entities
- Accept queries from remote entities and initiate image transfers as directed from those entities
- Issue and accept verification messages

VM PACS is a server application along with a viewing application.

VM PACS provides a user interface for system configuration and monitoring by system administrators, and a an application for diagnostic image display and image review

2.1.1 VM PACS

VM PACS is an affordable and scalable **Picture Archiving and Communication** System designed to optimize imaging workflow and simplify image management

Use a powerful PostgreSQL database engine as client server data. The system architecture scalable, allowing to add storage media according to the volume of studies intended to store and be access online. This gives the possibility to increase gradually the investment in hardware storage as needed.

All Image Storage and communications are according to the Dicom Standard. A configuration interface allows the system administrator to set the Application Entity Title (AE-TITLE) and listening port for the Dicom Communications with other devices

To protect the studies PACS has a full-featured fully automatic and programmable backup instance.

VM PACS is capable to send query and retrieve studies from other Dicom Applications using the DICOM 3.0 standard toolkits and enables the application to process standard inbound DICOM transmissions over TCP/IP. For Monitoring the Dicom traffic, incorporating a tool which shows all the DICOM transfers in a lapse of time, also VM PACS can be set to auto send studies to other Dicom Application Entities (AEs), depending on the modality, the description, the patient, or any other Dicom Tag selected and also can send all the previous studies from the same patient to a target Dicom AE.

This component is supported on Microsoft Windows Server 2003/2008/2012 in 32 bits or 64 bits.

2.1.2 VM Medical Workstation

VM Medical Workstation provides all the necessary tools needed for image diagnosis, is compatible with over windows XP and higher.
VM Medical WS allows the user to visualize; report and print images and studies, whit a complete set of tools designed for diagnose medical images.
VM Medical Workstation includes a report module to archive the diagnostic results, linked to the informed study.

VM Medical WS allows the authorized user to burn studies in a CD/DVD along with the study is an autorun software with diagnostic Dicom tools. If the study has a report, this report is attached to the CD/DVD in a PDF format.

The software also include an Advance Printing tool which allows the user to perform a personalized layout, changing window & Level, zoom, and pan to one or all images in the layout.

2.1.3 VM Clinical Viewer

VM Clinical Viewer is the web access interface of VM PACS and runs on Tomcat webserver, allows integration with any Operating System, and allows the institution to access the images remotely. Access protocols must include standard HTTP.

VM Clinical Viewer improves the specialist consultation and the communication between radiologists and referring physicians from any location in the world. The system enables authorized external users to have access to specific patient studies.

2.2 Comparative features with predicative device

Predicate device: K123174 Centricity PACS (Manufacturer GE)

	VM PACS with VM Medical Workstation	Centricity PACS-IW with Universal Viewer K123174
DataBase	VM PACS Database architectures in tow main databases are managed by PostgreSQL. Databases Manages User Profiles, local configuration, and all Dicom data from the images, are stored in a filesystem. The DataBase component may run in Microsoft Windows Server 2003/2008/201232 or 64 bits.	The Centricity PACS-IW database instance (actually three databases) is managed by Microsoft SQL Server 2005. The database manages all system user profiles, as well as all study data, other than the physical images which are stored on the filesystem by the Storage Controller. The Database component may run on Microsoft SQL Server 2005 in either 32-bit or 64-bit mode, running on Microsoft Windows Server 2003 running in either 32-bit or 64-bit mode.
Intended Use	Software designed to receive, store, distribute, process and display Digital Imaging and Communications in Medicine (DICOM) and non- DICOM information and data throughout a clinical environment. Digital communication and storage of the images. Includes a Workstation capable of: Image processing, measurement and other diagnostics tools. The software performs digital communication and storage of the images and is meant to be administrated by a trained user.	Centricity PACS-IW with Universal Viewer is a device that displays medical images (including mammograms) and data from various imaging sources. Images and data can be viewed, communicated, processed and displayed within the system or across computer networks at distributed locations. The main categories of users to utilize Centricity PACS are: Radiologist, Technologist, Clinician, Referring Physician, Clinical Admin, radiological Residents, ED Physician, Clinical Staff and System Administrator The PACS-IW is not intended to be used by Patients.

Indications for use	*VM PACS is designed to Store Medical Dicom Images and leave them available to be used for diagnostics or transferred to other Dicom devices.* *VM PACS is not meant to create or modify DICOM images. VM PACS store the images and the Data Set send by an DICOM compatible image diagnostic equipment and store them making them available to be access by a workstation or viewer, or been transfer to another Dicom Compatible device.* *VM PACS does not modify the images store in it.* *User Graphic interface VM Medical Workstation is a complete Workstation which provides diagnostic tools for image diagnose, for CT, MR, PT, CR, DX, NM, MG, XA, RF, SC, US and ES, as zoom, Window & Level variation and presets, measurements and a complete set of diagnostics tools and includes a report tool for the studies.* *Lossy compressed mammographic images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA cleared display that meets technical specifications reviewed and accepted by FDA.* *VM Clinical Viewer is the web access interface of VM PACS, which allows integration with any Operating System, brings to the institution the capacity to access the images remotely.* *VM Clinical Viewer allows the specialist consultation and the communication between radiologists and referring physicians. The system enables authorized external users to have access to specific patient studies, is not intended for diagnostic purposes when used on mobile devices.*	Centricity PACS-IW is a medical software system that is intended for acquisition and storage of medical images and other information objects generated by the acquisition equipment (modalities) as well as other devices (postprocessing workstations). It allows multiple users to remotely access the images it stores, from compatible computers on a network, for the purpose of manipulation, diagnostic interpretation and post-diagnostic review of the images and other objects it stores. Centricity PACS-IW shall operate within operating environment that meets defined minimum specifications. The system allows users various methods of exporting information, including the original information it acquires as well as user work results. This includes sending images and other objects to the external systems over the network utilizing the DICOM protocol, saving them on CD in DICOM and Proprietary formats, printing of Key Images onto DICOM and Windows printers, printing Notes, Reports and other information on Windows printers. Centricity PACS-IW provides integration capabilities with other types of information systems in the Healthcare Enterprise (HIS, RIS, EMR, dictation and voice recognition systems). Centricity PACS-IW supports desktop integration with various Information systems to invoke modules of such system for display of supplementary information associated with the study selected within PACS-IW. The information may pertain to the specific study, order/visit or patient. The desktop integration can also be employed to perform certain operations (such as dictation of the diagnostic report) within external system Using information provided by the PACS-IW (for example, accession number of an order). PACS-IW, and subsequent storage of resulting DICOM objects within Centricity PACS-IW.
Users	Designed to be used by trained professionals, including but not limited to physicians, nurses and medical technicians.	Typical users of this system are trained professionals, including but not limited to radiologists, physicians, nurses, medical technicians, and assistants.
Modalities	all DICOM Modalities	all DICOM Modalities
Image Sources	Dicom, JPEG and JPEG 2000 compliant	Dicom, JPEG and JPEG 2000 compliant
Connectivity	TCP/IP	TCP/IP
OS Compatibility	The product target Operating System is Microsoft Windows /XP Professional/7/8 and Windows Server 2003/2008 supported physical media. Linux and iOS compatibility in the Web interface to access the studies	Operating System is Microsoft Windows /XP Professional/7/8, Windows Server 2003/2008, Linux and iOS compatibility. Web Access to the studies

2.3 Comparison to Predicative Device:

2.3.1 Comparison:

PREDICATE DEVICE: K123174 CENTRICITY PACS (MANUFACTURER: GE)

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