DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 3, 2017

Agfa HealthCare N.V.
% ShaeAnn Cavanagh, RAC
Regulatory Affairs Manager, North America
Agfa HealthCare Corporation
10 South Academy Street
GREENVILLE SC 29601

Re: K170434
Trade/Device Name: Enterprise Imaging XERO Viewer 8.1
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 30, 2017
Received: May 31, 2017

Dear Ms. Cavanagh:

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,

Robert Ochs, Ph.D.
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)*
K170434

Device Name

Enterprise Imaging XERO Viewer 8.1

Indications for Use *(Describe)*

Agfa HealthCare's Enterprise Imaging XERO Viewer 8.1 is a software application used for reference and diagnostic viewing of multi-specialty medical imaging and non-imaging data with associated reports and documents and, as such, fulfills a key role in the Enterprise Imaging solution. XERO Viewer 8.1 enables healthcare professionals, including (but not limited to) physicians, surgeons, nurses, and administrators to receive and view patient images, documents and data from multiple departments and organizations within one multi-disciplinary viewer. XERO Viewer 8.1 allows users to perform image manipulations (including window/level, markups, 3D visualization) and measurements.

When images are reviewed and used as an element of diagnosis, it is the responsibility of the trained physician to determine if the image quality is suitable for their clinical application. Lossy compressed mammography images and digitized film images should not be used for primary image interpretation. Uncompressed or non-lossy compressed "for presentation" images may be used for diagnosis or screening on monitors that are FDA-cleared for their intended use.

XERO Viewer 8.1 can optionally be configured for Full Fidelity Mobile, which is intended for mobile diagnostic use, review and analysis of CR, DX, CT, MR, US, ECG images and medical reports. XERO Viewer Full Fidelity Mobile is not intended to replace full diagnostic workstations and should only be used when there is no access to a workstation. XERO Viewer Full Fidelity Mobile is not intended for the display of mammography images for diagnosis.

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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510(K) SUMMARY:

Agfa HealthCare's
Enterprise Imaging XERO Viewer

I. SUBMITTER

Agfa HealthCare N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Jodi Coleman, Prepared: February 10, 2017
Telephone: 519-746-6210 ext 2485

II. DEVICE

Name of Device: Enterprise Imaging XERO Viewer 8.1
Common Name: System, Image Processing, Radiological
Classification Name: Picture Archiving and Communications System (PACS)
Regulatory Classification: Class II, 21 CFR 892.2050
Product Code: LLZ

III. PREDICATE DEVICES

This is a 510(k) for Agfa's Enterprise Imaging, which is a picture archiving and communications system. It is substantially equivalent to Carestream Health's Vue Motion (K151774) and Agfa HealthCare's ICIS View (K143397).

These predicate devices have not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

Enterprise Imaging XERO Viewer is a web based software application used for reference and diagnostic viewing of multi-specialty medical imaging and non-imaging data with associated reports and documents. It is a picture archiving and communication system (PACS), product code LLZ, intended to provide an interface for the display, annotation, review, printing, storage and distribution of multimodality medical images, reports and demographic information for review and diagnostic purposes within the system and across computer networks. XERO Viewer enables authenticated users to search for and display patient studies (reports and images) using a web browser, user's do not need to download or install any additional software or plug-ins to use XERO Viewer.

It is the successor to Agfa's ICIS View predicate (K143397) and adds the following new functionality: it adds Xtend (extended study viewing) desktop diagnostic support for additional modalities, supports Xtend 3D visualization and ECG mobile (Full Fidelity) diagnostic support utilizing the newer iPad version.

The only difference of the new device and the primary predicate device, Carestream Vue Motion (K151774) is the new device does not support mobile diagnostic viewing on other handheld devices other than an iPad. Differences in devices do not alter the intended diagnostic effect.

Principles of operation and technological characteristics of the new and predicate devices are the same.

INTENDED USE

Agfa HealthCare's Enterprise Imaging XERO Viewer 8.1 is a software application used for reference and diagnostic viewing of multi-specialty medical imaging and non-imaging data with associated reports and documents and, as such, fulfills a key role in the Enterprise Imaging solution. XERO Viewer 8.1 enables healthcare professionals, including (but not limited to) physicians, surgeons, nurses, and administrators to receive and view patient images, documents and data from multiple departments and organizations within one multi-disciplinary viewer. XERO Viewer 8.1 allows users to perform image manipulations (including window/level, markups, 3D visualization) and measurements.

When images are reviewed and used as an element of diagnosis, it is the responsibility of the trained physician to determine if the image quality is suitable for their clinical application. Lossy compressed mammography images and digitized film images should not be used for primary image interpretation. Uncompressed or non-lossy compressed "for presentation" images may be used for diagnosis or screening on monitors that are FDA-cleared for their intended use.

XERO Viewer 8.1 can optionally be configured for Full Fidelity Mobile, which is intended for mobile diagnostic use, review and analysis of CR, DX, CT, MR, US, ECG images and medical reports. XERO Viewer Full Fidelity Mobile is not intended to replace full diagnostic workstations and should only be used when there is no access to a workstation. XERO Viewer Full Fidelity Mobile is not intended for the display of mammography images for diagnosis.

Intended use has not changed as a result of any labeling modification(s).

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

Agfa's Enterprise Imaging XERO Viewer has an Indications For Use statement similar to predicate devices (K151774, K143397)). The statements have been combined and simplified. The devices have the same technological characteristics.

Both XERO Viewer and the primary predicate device, Carestream Vue Motion (K151774) are used to display medical images for diagnostic purposes of multiple modalities. Both provide wireless and portable access to medical images on select validated mobile devices. Furthermore, XERO Viewer Full Fidelity and Vue Motion contain a statement that it is not intended to replace full diagnostic workstations and should only be used when there is no access to a workstation. XERO Viewer and Vue Motion (K151774) are indicated to allow image manipulations, 3D viewing capabilities and display lossy/lossless images. Both XERO Viewer and Vue Motion (K151774) require the use of FDA approved display hardware for primary interpretation and review of mammography images.

Enterprise Imaging XERO Viewer is a web based software application used for reference and diagnostic viewing of multi-specialty medical imaging and non-imaging data with associated reports and documents. It is a picture archiving and communication system (PACS), product code LLZ, intended to provide an interface for the display, annotation, review, printing, storage and distribution of multimodality medical images, reports and demographic information for review and diagnostic purposes within the system and across computer networks. XERO Viewer enables authenticated users to search for and display patient studies (reports and images) using a web browser, user's do not need to download or install any additional software or plug-ins to use XERO Viewer.

It is the successor to Agfa's ICIS View predicate (K143397) and adds the following new functionality: it adds Xtend (extended study viewing) desktop diagnostic support for additional modalities, supports Xtend 3D visualization and ECG mobile (Full Fidelity) diagnostic support utilizing the newer iPad version.

The only difference of the new device and the primary predicate device, Carestream Vue Motion (K151774) is the new device does not support mobile diagnostic viewing on other handheld devices other than an iPad. Differences in devices do not alter the intended diagnostic effect.

The devices have the same technological characteristics. The new device and the predicate devices (K151774, K143397) are picture archiving and communication systems (PACS), Product Code LLZ. Agfa's XERO Viewer system is substantially equivalent to the predicate devices (K151774, K143397) in that it uses precisely the same technology to capture and display medical data.

Descriptive characteristics and performance data including image quality evaluations by qualified radiologists are adequate to ensure equivalence. Differences in devices do not alter the intended therapeutic/diagnostic effect.

Table 1 on the next page summarizes the similarities and differences between the new device and predicates.

	Enterprise Imaging XERO Viewer **NEW DEVICE**	**Carestream Vue Motion (K151774) PRIMARY PREDICATE**	**Agfa HealthCare's ICIS View (K143397)**
Communication	Same as predicates	DICOM	DICOM
Modalities	Including CR, DX, CT, MR, US, ECG	Including CR, DR, CT, MR, NM, US, ECG	CR, DX, CT, MR, US
Modalities Full Fidelity Mobile Diagnostic	CR, DX, CT, MR, US, ECG	Including CR, DR, CT, MR, NM, US, ECG	CR, DX, CT, MR, US
Mammography Use	Same as primary predicate	Yes	No
Mobile Device Support for Diagnostic Viewing	iPads	iPads, iPhones, Galaxy Note, Galaxy S	iPads
Transfer/Storage/Display of Medical Images	Same as predicates	Yes	Yes
Network Access	Web browser connects to existing PACS	Web browser connects to existing PACS	Web browser connects to existing PACS
User Authentication	Same as primary predicate	Yes	Yes
Window Level	Same as primary predicate	Yes	Yes
Rotate/Pan/Zoom	Same as primary predicate	Yes	Yes
Measurement	Same as primary predicate	Yes	Yes
Annotation	Same as primary predicate	Yes	Yes
3D Visualization	Same as primary predicate	Yes	No
Indications for Use	Software application used for reference and diagnostic viewing of multispecialty medical imaging and non-imaging data with associated reports and documents and, as such, fulfills a key role in the Enterprise Imaging solution. Enables healthcare professionals, including (but not limited to) physicians, surgeons, nurses, and administrators to receive and view patient images, documents and data from multiple departments and organizations within one multidisciplinary viewer. Viewer allows users to perform image manipulations (including window/level, markups, 3D visualization) and measurements. When images are reviewed and used as an element of diagnosis, it is the responsibility of the trained physician to determine if the image quality is suitable for their clinical application. Lossy compressed mammography	Program is used for patient management by clinicians in order to access and display patient data, medical reports, medical data, and medical images for diagnosis from different modalities including CR, DR, CT, MR, NM, ECG, and US. Provides wireless and portable access to medical images for remote reading or referral purposes from web browsers including usage with validated mobile devices. Not intended to replace full workstations	ICIS® View is a software application used for reference viewing of medical images and associated reports and, as such, fulfills a key role in Agfa HealthCare's Imaging Clinical Information System (ICIS). ICIS® View enables healthcare professionals, including (but not limited to) physicians, surgeons, nurses, and administrators to receive and view patient images and data from multiple departments and organizations within one multi-disciplinary viewer. Users may access the product directly via a web-browser, select mobile devices, healthcare portal or within the Electronic Medical Record (EMR). ICIS® View allows users to perform basic image manipulations and measurements (for example

	Enterprise Imaging XERO Viewer **NEW DEVICE**	**Carestream Vue Motion (K151774) PRIMARY PREDICATE**	**Agfa HealthCare's ICIS View (K143397)**
	images and digitized film images should not be used for primary image interpretation. Uncompressed or non-lossy compressed "for presentation" images may be used for diagnosis or screening on monitors that are FDA cleared for their intended use. Can optionally be configured for Full Fidelity Mobile, which is intended for mobile diagnostic use, review and analysis of CR, DX, CT, MR, US, ECG images and medical reports. Full Fidelity Mobile is not intended to replace full diagnostic workstations and should only be used when there is no access to a workstation. Full Fidelity Mobile is not intended for the display of mammography images for diagnosis.	and should be used only when there is no access to a workstation. For primary interpretation and review of mammography images, only use display hardware that is specifically designed for and cleared by FDA for mammography.	window/level, rotation, zoom, and markups). ICIS® View can optionally be configured for Full Fidelity mode, which is intended for diagnostic use, review and analysis of CR, DX, CT, MR, US images and medical reports. ICIS® View Full Fidelity is not intended to replace full diagnostic workstations and should only be used when there is no access to a workstation. ICIS® View full fidelity is not intended for the display of digital mammography images for diagnosis.

Table 1: Device Comparison Table

VI. PERFORMANCE DATA

Verification and validation testing confirmed the device meets performance, safety, usability and security requirements. No clinical trials were performed in the development of the device.

There are no applicable FDA mandated performance standards for this device. However, Agfa's in-house standard operating procedures were used for the development of the software; these procedures conform to the following standards:

- ISO 13485:2003 Medical Devices - Quality Management Systems
- ISO 14971:2012 Application of Risk Management to Medical Devices
- ISO 27001:2013 Information Security Management
- ISO 62366:2007 Medical Devices – Application of usability engineering to medical devices
- IEC 62304:2006 Medical Device Software – Software life cycle processes
- ACR/NEMA PS3.1-3.20: 2011 Digital Imaging and Communications in Medicine (DICOM)

Laboratory testing and software testing (for a moderate level of concern device) using equivalent test protocols as used for Medical Image Management Devices as part of verification and validation under design controls (according to 21 CFR 820.30).

No animal or clinical studies were performed in the development of the new device. No patient treatment was provided or withheld.

XERO Viewer vs. Agfa Enterprise Imaging Desktops (K142316) - Requirements & Performance of Xtend (full fidelity) diagnostic desktop viewing were evaluated (note Xtend Full Fidelity is not supported on mobile devices):

To determine substantial equivalence, diagnostic image quality was evaluated by qualified medical professionals comparing images across 2 platforms:

- Enterprise Imaging 8.0.0 Diagnostic Desktop (K142316) – using an FDA cleared diagnostic monitor
- XERO Viewer Xtend full fidelity – using an FDA cleared diagnostic monitor

A sample set of an average of 5 or 6 imaging studies per modality were evaluated. Qualified radiologists were asked to provide an overall score when comparing the diagnostic image quality in XERO Viewer to the Enterprise Imaging Diagnostic Desktop. The executed validation plan for image quality was performed on calibrated diagnostic display devices.

To evaluate ECG viewing users were asked to display ECG's in DICOM and PDF formats, change layouts, adjust waveforms and use the tools provided (zoom, measurements). Validation and non-clinical (bench) testing was performed on an iPad mobile device to ensure that the views and functionality performed consistently between desktop and a mobile platform.

Performance data including image quality evaluations by qualified radiologists are adequate to ensure equivalence to the predicate.

Summary

Based on the performance data as documented in the above testing, XERO Viewer is found to have a safety and effectiveness profile that is similar to the predicate device.

VII. CONCLUSIONS

The device has indications for use that are consistent with those of the legally marketed predicate device. Where technological characteristics differ lab tests concluded that the device is substantially equivalent to the predicate in that it does not alter the intended therapeutic/diagnostic effect.

This 510(k) has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.