DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 22, 2016

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

Re: K161061
Trade/Device Name: IMPAX Volume Viewing 4.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 8, 2016
Received: June 8, 2016

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 yours,

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

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)*
K161061

Device Name
IMPAX Volume Viewing 4.0

Indications for Use *(Describe)*
The Volume Viewing software is a visualization package for PACS workstations. It is intended to support the medical professional in the reading, analysis and diagnosis of DICOM compliant volumetric medical datasets. The software is intended as a general purpose digital medical image processing tool, with optional functionality to facilitate visualization and measurement of vessel features.

Other optional functionality is intended for the registration of anatomical (CT) on a second CT dataset or on functional volumetric image data (MR) to facilitate the comparison of various lesions. Volume and distance measurements are intended for evaluation and quantification of tumour measurements, and other analysis and evaluation of both hard and soft tissues. The software also supports interactive segmentation of a region of interest (ROI), has a dedicated tool set for lung lesion segmentation, quantification and follow-up of lesions selected by the user and provides tools to define and edit paths such as centerlines through structures, which may be used to analyze cross-sections of structures, or to provide flythrough visualizations rendered along such centerline.

Caution: Web-browser access is available for review purposes. Images accessed through a web-browser (via a mobile device or by other means) should not be used to create a diagnosis, treatment plan, or other decision that may affect patient care.

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 IMPAX Volume Viewing 4.0

I. SUBMITTER

Agfa HealthCare N.V.
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Belgium
Contact: Koen Cobbaert, Prepared: April 14, 2016
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II. DEVICE

Name of Device: IMPAX Volume Viewing 4.0
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 IMPAX Volume Viewing 4.0, which is a picture archiving and communications system. It is substantially equivalent to Agfa's IMPAX Volume Viewing 3.0 (K133135) and TeraRecon's iNtuition 4.4.11 (K121916).

These predicates have not been subject to a design-related recall. No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

IMPAX Volume Viewing is a general purpose medical image processing tool for the reading and analysis of 3D image datasets. It is also intended for the registration of anatomical (CT) image data onto functional (MR) data to facilitate the comparison of various lesions. Volume and distance measurements facilitate the quantification of lesions and the analysis of both soft and hard tissue.

A variant of the software also provides web-browser access for review purposes. Images accessed through a web-browser (via a mobile device or by other means) should not be used to create a diagnosis, treatment plan, or other decision that may affect patient care.

The new device is similar to the predicate devices. All are PACS system accessories that allow the user to view and manipulate 3D image data sets. This new version adds a dedicated tool set for lesion management and flythrough visualizations rendered along a centerline for endoscopic view of vessels and airways.

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

INTENDED USE

The Volume Viewing software is a visualization package for PACS workstations. It is intended to support the medical professional in the reading, analysis and diagnosis of DICOM compliant volumetric medical datasets. The software is intended as a general purpose digital medical image processing tool, with optional functionality to facilitate visualization and measurement of vessel features.

Other optional functionality is intended for the registration of anatomical (CT) on a second CT dataset or on functional volumetric image data (MR) to facilitate the comparison of various lesions. Volume and distance measurements are intended for evaluation and quantification of tumour measurements, and other analysis and evaluation of both hard and soft tissues. The software also supports interactive segmentation of a region of interest (ROI), has a dedicated tool set for lung lesion segmentation, quantification and follow-up of lesions selected by the user and provides tools to define and edit paths such as centerlines through structures, which may be used to analyze cross-sections of structures, or to provide flythrough visualizations rendered along such centerline.

Caution: Web-browser access is available for review purposes. Images accessed through a web-browser (via a mobile device or by other means) should not be used to create a diagnosis, treatment plan, or other decision that may affect patient care.

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

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

Agfa's IMPAX Volume Viewing 4.0 has an Indication for Use statement largely similar to the statements for the predicate devices (K133135, K121916). Intended uses are the same. As software accessories to PACS systems, the predicates and the new device have the same technological characteristics. The software is used to identify characteristic patterns within 3D image data which the user can then view and manipulate.

IMPAX Volume Viewing 4.0 comprises the same functionality to manipulate and analyze 3D image data as its primary predicate IMPAX Volume Viewing 3.0. The device subject of this submission however differs on the following technological characteristics:

1. The visualization algorithm for multi-planar reformatting (MPR) now employs a different interpolation. MPR visualization is present in the primary predicate IMPAX Volume Viewing 3.0, but uses a different algorithm.
2. It includes additional visualization tools for fly-through along a centerline intended for endoscopic viewing of vessels and airways. This functionality is present in the secondary predicate TeraRecon's inNuition, but uses proprietary algorithms.
3. New tools were added for the automated segmentation and management of lung lesions. This functionality is present in the secondary predicate TeraRecon's inNuition, but uses proprietary algorithms.

Descriptive characteristics and performance data are adequate to ensure equivalence.

Differences in devices do not alter the intended therapeutic/diagnostic effect.

IMPAX Volume Viewing 4.0 is an accessory to Agfa's IMPAX PACS systems. It is a general

purpose medical image processing tool for the reading and analysis of 3D image datasets. It is the successor to Agfa's Volume Viewing 3.0 (K133135) and adds the following new functionality: a dedicated tool set for lung lesion segmentation, quantification and follow-up of lesions selected by the user and tools to define and edit paths such as centerlines through structures, which may be used to analyze cross-sections of structures, or to provide flythrough visualizations rendered along such centerline.

It is a tool for conveniently viewing and manipulating cross-sectional image series for display in any orientation and slice thickness. A second series can be registered or fused to the first automated, manually or with user defined landmarks. Automated table removal, removal of bone-like structures and segmentation of blood vessels and air-filled structures facilitate the visualization of vessels and airways. The software includes measurement tools for stenosis and lesions. A web-browser variant with a limited tool set provides remote access for review purposes.

In addition the software provides color maps, subtraction views, multiple screen layouts and anaglyphic images. Anaglyphic images are used to provide a stereoscopic 3D effect, when viewed with glasses where the two lenses are different (usually chromatically opposite) colors, such as red and cyan. Images are made up of two color layers, superimposed, but offset with respect to each other to produce a depth effect. The stereoscopic 3D view is available next to the "regular" 3D view. A user can toggle the image from the regular 3D view to stereo 3D. Tests by medical professionals showed that there are no specific medical or clinical benefits to using the stereoscopic 3D view. It is perceived as useful to train medical students, but has no clinical benefits in comparison to the "regular" 3D view.

The table on the next page summarizes the similarities and differences between the new device and the predicates.

	IMPAX Volume Viewing 4.0 NEW DEVICE	IMPAX Volume Viewing 3.0 (K133135) PRIMARY PREDICATE	TeraRecon iNtuition 4.4.11 (K121916) PREDICATE
3D Volume rendering	SAME AS PREDICATES	√	√
MPR, CPR	SAME AS PREDICATES	√	√
MIP, MinIP, AvgIP	SAME AS PREDICATES	√	√
Fusion and subtraction views	SAME AS PREDICATES	√	√
Can load and register two data sets for comparison (landmark based, automated, manual)	SAME AS PREDICATES	√	√
Multi-modality (CT and MR) image registration	SAME AS PREDICATES	√	√
Anaglyphic stereo 3D Viewing	SAME AS PREDICATES	√	√
Segmentation tools	SAME AS PREDICATES	√	√
Automated removal of the CT-table	SAME AS PREDICATES	√	√
Automated removal of bone-like structures	SAME AS PREDICATES	√	√
Volume measurements	SAME AS PREDICATES	√	√
Semi-automatied region growing	SAME AS PREDICATES	√	√
Vessel analysis	SAME AS PREDICATES	√	√
Stenosis measurements	SAME AS PREDICATES	√	√
AVI movie generation	SAME AS PREDICATES	√	√
Reformat to a new dataset	SAME AS PREDICATES	√	√
Color maps & Annotations	SAME AS PREDICATES	√	√
Intra- or internet access for review purposes (mobile use)	SAME AS PREDICATES	√	√
Lesion Management Module	SAME AS K121916	X	√
Automated lung nodule segmentation	SAME AS K121916	X	√
Endoscopic fly-through for vessels and airways	SAME AS K121916	X	√
Calcium Scoring of atherosclerotic plaque	SAME AS K133135	X	√
Interpretation of mammography images	SAME AS K133135	X	√
Tumor evaluation using RECIST criteria	SAME AS K133135	X	√

	IMPAX Volume Viewing 4.0 NEW DEVICE	**IMPAX Volume Viewing 3.0 (K133135) PRIMARY PREDICATE**	**TeraRecon iNtuition 4.4.11 (K121916) PREDICATE**
Liver measurements	SAME AS K133135	X	√
Time-Volume Analysis (TVA), Cardiac function and Time Dependent Analysis (TDA) of blood flow	SAME AS K133135	X	√
Tools for Endovascular Aortic Repair (for stent placement)	SAME AS K133135	X	√
Virtual Colonoscopy	SAME AS K133135	X	√
User interface	SAME AS K133135	IMPAX	iNtuition
Indications for Use	1. Visualization package for PACS workstations. 2. Support the medical professional in the reading, analysis and diagnosis of DICOM compliant volumetric medical datasets. 3. General purpose digital medical image processing tool, with optional functionality to facilitate visualization and measurement of vessel features. 4. Optional functionality - registration of anatomical (CT) on a second CT dataset or on functional volumetric image data (MR) to facilitate the comparison of various lesions. Volume and distance measurements - evaluation and quantification of tumor measurements, and other analysis and evaluation of both hard and soft tissues. 5. Supports interactive segmentation of a region of interest (ROI), has a dedicated tool set for lung lesion segmentation, quantification and follow-up of lesions selected by the user and provides tools to define and edit paths such as centerlines through structures. 6. Web-browser access is	1. Visualization package for PACS workstations. 2. Support the medical professional in the reading, analysis and diagnosis of DICOM compliant volumetric medical datasets. 3. General purpose digital medical image processing tool, with optional functionality to facilitate visualization and measurement of vessel features. 4. Optional functionality - registration of anatomical (CT) on a second CT dataset or on functional volumetric image data (MR) to facilitate the comparison of various lesions. Volume and distance measurements - evaluation and quantification of tumor measurements, and other analysis and evaluation of both hard and soft tissues. 5. Supports interactive segmentation of a region of interest (ROI). 6. Web-browser access is available for review purposes. Images	1. Provide access to images via client-server software, web browser and mobile technology. 2. Support healthcare professionals assist physicians in diagnosis by receiving, storing, transmitting, post-processing, displaying and allowing manipulation of reports and medical images from acquisition devices, including optical or other non-DICOM format images. 3. Visualization in combination of 2D, 3D and 4D are supported for single or multiple datasets. 4. Tools are provided to define and edit paths through structures such as centerlines, which may be used to analyze cross-sections of structures, or to provide flythrough visualizations rendered. Region Segmentation and quantitative analysis tools - images of vasculature, pathology and morphology and tracking of quantities over time. 5. Database - track and compare results using published comparison techniques. Calcium scoring for quantification of atherosclerotic plaque and digital image processing to derive metadata or new images from input image sets are supported. Image processing - extract metadata to derive parametric images from combinations of multiple input images. 6. Interpretation of mammographic images or digitized film screen images is only supported when software is

	IMPAX Volume Viewing 4.0 NEW DEVICE	IMPAX Volume Viewing 3.0 (K133135) PRIMARY PREDICATE	TeraRecon iNtuition 4.4.11 (K121916) PREDICATE
	available for review purposes. Images accessed through a web-browser (via a mobile device or by other means) should not be used to create a diagnosis, treatment plan, or other decision that may affect patient care.	accessed through a web-browser (via a mobile device or by other means) should not be used to create a diagnosis, treatment plan, or other decision that may affect patient care.	used without compression and with an FDA-Approved monitor. Not intended to replace full workstations and should only be used when there is no access to a workstation. Not intended for web-browser or mobile diagnostic use.

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 14971:2007 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

Verification

Verification tests for IMPAX Clinical Applications 4.0 covered all requirements and identified risk control measures.

Regression testing assured the different measurement algorithms still provide the same output as the previous version IMPAX Volume Viewing 3.0 (K133135). Testers made identical measurements of diameters, areas and volumes and compared those against reference values. Results met the established acceptance criteria of +/- scanner resolution (for dataset uncertainty).

The tests also included crosshair position checks to verify whether viewports link to the same location in every dataset. Results met the established acceptance criteria of half a voxel (for rounding differences across graphic video cards).

Validation

Agfa invited 3 radiologists from several Belgian hospitals to its facilities to evaluate the new functionality. In a lab environment the radiologists selected and loaded representative clinical

datasets on IMPAX Clinical Applications 4.0 and its predicate devices. They executed typical workflows and scored the features under investigation. A scoring scale was implemented and acceptance criteria established. Results met acceptance criteria.

The tests concluded that IMPAX Clinical Applications 4.0 is substantially equivalent to the predicate iNtuition 4.4.11 in terms of endoscopic viewing of tubular structures (vessels and airways) and to the predicate IMPAX Volume Viewing 3.0 in terms of image rendering. Also the accuracy of the lung nodule segmentation and the capabilities of the lesion management module were scored. These features were found to be adequate to segment lesions, analyze them and follow-up on their growth over the time.

All verification and validation testing has been successfully completed.

Summary

Based on the performance data as documented in the above testing, IMPAX Volume Viewing 4.0 is found to have a safety and effectiveness profile that is similar to the predicate devices.

VII. CONCLUSIONS

The device has indications for use that are consistent with those of the legally marketed predicate devices. Where technological characteristics differ lab tests concluded that the device is substantially equivalent to the predicates 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.