AGFA HealthCare N.V.
Jodi Coleman
Director Premarket QARA
Septestraat 27
Mortsel, B-2640
Belgium

October 15, 2025

Re: K252199
Trade/Device Name: AGFA HealthCare Enterprise Imaging
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: October 1, 2025
Received: October 1, 2025

Dear Jodi Coleman:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn

(https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Lamb, Ph.D.
Assistant Director
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K252199

Device Name
AGFA HealthCare Enterprise Imaging

Indications for Use *(Describe)*
Enterprise Imaging Desktops when deployed as a departmental Picture Archiving and Communications System (PACS) provides an interface for the acquisition, display, digital processing, annotation, review, printing, storage and distribution of multimodality medical images, reports and demographic information for diagnostic purposes within the system and across computer networks. Enterprise Imaging Desktops are intended to be used by trained healthcare professionals including, but not limited to physicians, radiologists, orthopaedic surgeons, cardiologists, mammographers, technologists, and clinicians for diagnosis and treatment planning using DICOM compliant medical images and other healthcare data.

MPR, MIP and 3D rendering functionality allows the user to view image data from perspectives different from that in which it was acquired. Other digital image processing functionality such as multi-scale window leveling, image registration and segmentation can be used to enhance image viewing. Automatic spine labelling provides the capability to semi-automatically label vertebrae or disks.

As a comprehensive imaging suite, Enterprise Imaging Desktops integrates with servers, archives, Radiology Information Systems (RIS), Cardiology Information Systems (CIS), Hospital Information Systems (HIS), Electronic Patient Records (EPR), reporting and 3rd party applications for customer specific workflows.

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 mammographic use.

When deployed as a hospital-wide Solution (Enterprise Imaging for Multispecialty Departments), Agfa HealthCare’s Enterprise Imaging Desktops provides order generation, image acquisition, quality control, image reading, reporting, and review workflows for departments that have no such systems available including (but not limited to) dermatology, ophthalmology, gastroenterology, dental and general hospital use.

AGFA HealthCare’s Enterprise Imaging XERO Viewer is a 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. XERO Viewer 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 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 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary – AGFA HealthCare Enterprise Imaging

**Submitter**

AGFA HealthCare N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Jodi Coleman
Phone: (519) 591-1161
Email: jodi.coleman@agfa.com
Submission prepared: July 14, 2025

**Device**

Trade Name: AGFA HealthCare Enterprise Imaging
Common Name: System, Image Processing, Radiological
Regulation Number: 21 CFR 892.2050
Classification Name: Medical image management and processing system
Device Class: Class II
Product Code: LLZ

**Predicate Devices**

This is a 510(k) for AGFA HealthCare Enterprise Imaging, it is substantially equivalent to K133135 – AGFA HealthCare's IMPAX Volume Viewing (Primary Predicate), K142316 – AGFA HealthCare's Enterprise Imaging Desktops, and K170434 – AGFA HealthCare's Enterprise Imaging XERO Viewer.

**Device Description**

This premarket notification is for AFGA HealthCare's Enterprise Imaging - Vessel Tracking functionality. The Vessel Tracking functionality is available in both AGFA HealthCare's Enterprise Imaging Desktops product and Enterprise Imaging XERO Viewer product.

Enterprise Imaging is a standalone software device (SaMD). AGFA HealthCare Enterprise Imaging Vessel Tracking functionality provides the capability to automatically create vessel centrelines, read the contour points and angles as well as provide minimum and maximum diameter of cross sections.

AGFA HealthCare's Enterprise Imaging Desktops is a medical image management and processing system (MIMPS), product code LLZ, which provides an interface for the acquisition, display, digital processing, annotation, review, printing, storage and distribution of multimodality medical images, reports and demographic information for diagnostic purposes within the system and across computer networks.

AGFA HealthCare's XERO Viewer is a medical image management and processing system (MIMPS), product code LLZ, which is a web based software application used for reference and diagnostic viewing of multispecialty medical imaging and non-imaging data with associated reports and documents. XERO Viewer enables healthcare professionals to receive and view patient images, documents and data from multiple departments and organizations within one multi-disciplinary viewer.

AGFA HealthCare's Enterprise Imaging Vessel Tracking adds the following new functionality available in both AGFA HealthCare's Enterprise Imaging Desktops product and Enterprise Imaging XERO Viewer product: a vessel analysis tool that provides the capability to automatically create vessel centrelines that can be used to monitor and analyze the progression of vascular diseases.

Vessel tracking is new functionality not included in the previous 510(k) clearances for Enterprise Imaging Desktops and Enterprise Imaging XERO Viewer. The vessel tracking algorithm however was previously included in AGFA HealthCare's IMPAX Volume Viewing 3.0 510(k) primary predicate K133135. The new device is substantially equivalent to the primary predicate device's (K133135) vessel analysis functionality.

**Intended Use/Indications for Use**

Enterprise Imaging Desktops when deployed as a departmental Picture Archiving and Communications System (PACS) provides an interface for the acquisition, display, digital processing, annotation, review, printing, storage and distribution of multimodality medical images, reports and demographic information for diagnostic purposes within the system and across computer networks. Enterprise Imaging Desktops are intended to be used by trained healthcare professionals including, but not limited to physicians, radiologists, orthopaedic surgeons, cardiologists, mammographers, technologists, and clinicians for diagnosis and treatment planning using DICOM compliant medical images and other healthcare data.

MPR, MIP and 3D rendering functionality allows the user to view image data from perspectives different from that in which it was acquired. Other digital image processing functionality such as multi-scale window leveling, image registration and segmentation can be used to enhance image viewing. Automatic spine labelling provides the capability to semi-automatically label vertebrae or disks.

As a comprehensive imaging suite, Enterprise Imaging Desktops integrates with servers, archives, Radiology Information Systems (RIS), Cardiology Information Systems (CIS), Hospital Information Systems (HIS), Electronic Patient Records (EPR), reporting and 3$^{rd}$ party applications for customer specific workflows.

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 mammographic use.

When deployed as a hospital-wide Solution (Enterprise Imaging for Multispecialty Departments), Agfa HealthCare's Enterprise Imaging Desktops provides order generation, image acquisition, quality control, image reading, reporting, and review workflows for departments that have no such systems available including (but not limited to) dermatology, ophthalmology, gastroenterology, dental and general hospital use.

AGFA HealthCare's Enterprise Imaging XERO Viewer is a 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. XERO Viewer 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 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 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.

**Technological Comparison**

This pre-market submission will demonstrate 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.

This premarket notification is for AFGA HealthCare's Enterprise Imaging - Vessel Tracking functionality. The Vessel Tracking functionality is available in both AGFA HealthCare's Enterprise Imaging Desktops product and Enterprise Imaging XERO Viewer product.

AGFA HealthCare's Enterprise Imaging Vessel Tracking adds the following new functionality: a vessel analysis tool that provides the capability to automatically create vessel centrelines that can be used to monitor and analyze the progression of vascular diseases.

Vessel tracking is new functionality not included in the previous 510(k) clearances for Enterprise Imaging Desktops and Enterprise Imaging XERO Viewer. The vessel tracking algorithm however was previously included in AGFA HealthCare's IMPAX Volume Viewing 3.0 510(k) primary predicate K133135. The new device is substantially equivalent to the primary predicate device's (K133135) vessel analysis functionality.

Table 1 below summarizes the similarities and differences between the new device and predicate devices:

| | **Enterprise Imaging Solution (Vessel tracking) (K252199)** | **IMPAX Volume Viewing 3.0 (K133135) PRIMARY** | **IMPAX Agility 2014 (K142316)** | **Enterprise Imaging XERO Viewer 8.x (K170434)** |
|---|---|---|---|---|
| **Communications** | DICOM | DICOM | DICOM | DICOM |
| **Operating system** | Windows 10, 11 | - | Windows 7, 8.1 | Windows 10 |
| **Network Access** | √ | √ | √ | √ |

| | Enterprise Imaging Solution (Vessel tracking) (K252199) | IMPAX Volume Viewing 3.0 (K133135) PRIMARY | IMPAX Agility 2014 (K142316) | Enterprise Imaging XERO Viewer 8.x (K170434) |
|---|---|---|---|---|
| **Multiple displays** | √ | √ | √ | √ |
| **Window Level** | √ | - | √ | √ |
| **Pan/Zoom/Rotate** | √ | - | √ | √ |
| **Calibrate/Measure** | √ | √ | √ | √ |
| **Annotate** | √ | √ | √ | √ |
| **MIP, MPR** | √ | √ | √ | √ |
| **3D Rendering** | √ | √ | √ | √ |
| **Workflow orchestration** | √ | - | √ | √ |
| **3D Registration (load and register two datasets for comparison)** | √ | √ | √ | √ |
| **Vessel Tracking** | √ | √<br>(Primary predicate for Vessel Tracking functionality) | - | - |

**Table 1 – Device Comparison Table**

The device is the successor to the AGFA HealthCare's Enterprise Imaging Desktops (IMPAX Agility) predicate (K142316) and AGFA HealthCare's Enterprise Imaging XERO Viewer 8.1 predicate (K170434). The new device is substantially equivalent to the primary predicate device's (K133135) vessel analysis functionality.

IMPAX Volume Viewing (K133135) is a visualization package for PACS workstations, the vessel analysis algorithm is the same algorithm in the new device and the primary predicate device, therefore the devices have the same technological characteristics for vessel tracking.

Principles of operation and technological characteristics of the new and predicate devices are the same. There is no change to the intended use of the device vs. the predicate devices. Laboratory data including, performance assessments and evaluations conducted with qualified radiologists confirm that performance is substantially equivalent to the predicate.

**Non-Clinical and/or Clinical Tests Summary**

AGFA HealthCare has tested the device to confirm it meets specifications and operates as planned.

Validation activities of the Vessel Tracking functionality were performed in a simulated clinical environment. Validation focused on key scenarios for creating a centreline, where each scenario was evaluated with feedback collected from end users.

Based on the verification and validation results, the testing has passed successfully. The verification and validation acceptance criteria have been fully achieved, confirming the tool's accuracy, effectiveness and suitability for clinical use.

Performance data including evaluations by qualified radiologists are adequate to ensure substantial equivalence. No clinical trials were performed in the development of the device. No patient treatment was provided or withheld.

**Conclusions**

The device has indications for use that are consistent with those of the legally marketed predicate device. Verification and validation results have concluded that the device is substantially equivalent to the predicate device.

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.