November 18, 2021

Agfa N.V.
℅ Ms. ShaeAnn Cavanagh
Regulatory Affairs Manager
Agfa US Corp.
10 South Academy Street
GREENVILLE SC 29601

Re: K213469
Trade/Device Name: VALORY
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: October 27, 2021
Received: October 28, 2021

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

, for

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213469

Device Name
VALORY

Indications for Use *(Describe)*
The VALORY system is a General Radiography X-ray imaging system used in hospitals, clinics and medical practices by radiographers, radiologists and physicists to make, process and view static X-ray radiographic images of the skeleton (including skull, spinal column and extremities), chest, abdomen and other body parts on adults and pediatric patients.

Applications can be performed with the patient in sitting, standing or lying position.

The system is not intended for use in Mammography applications

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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5. 510(K) Summary

510(K) SUMMARY

Agfa N.V.
VALORY

I. SUBMITTER

Agfa N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Wim Govaerts, Prepared: October 27, 2021
Telephone: + 32 3444 6246

II. DEVICE

Name of Device: VALORY

Common Name: Solid-State X-Ray Imager (Flat Panel/Digital Imager)
Classification Name: Stationary X-ray System
Regulatory Classification: Class II, 21 CFR 892.1680
Product Code: MQB

III. PREDICATE DEVICE(S)

This is a 510(k) for Agfa's VALORY system which is a solid state x-ray system, a direct radiography (DR) system. It is substantially equivalent to Agfa's predicate device, DR 600 (K152639).

Predicate Device: DR 600
Common Name: Solid-State X-Ray Imager (Flat Panel/Digital Imager)
Classification Name: Stationary X-ray System
Regulatory Classification: Class II, 21 CFR 892.1680
Product Code: MQB

The DR 600 predicate device has not been subject to a design-related recall. The DR 600 has been subject to two medical device reporting MDR) incidents and nine accidental radiation occurrence incidents (AROs). However, the MDR reported incidents and seven of the nine ARO incidents did not occur in the United States. The MDR incidents were isolated issues and no patient harm or user was reported during the event. The international ARO events involved erroneous collimator behavior not related to a design failure but it was determined to be operator error and the customer was retrained. An additional ARO event occurred in Canada due to a faulty hand switch. The hand switch was replaced and the system functioned as intended. No patient or user harm was reported during the events. The two domestic ARO incidents involved the wrong configuration setting for the AED function with the detector which compensated by doubling the mAs resulting in patients receiving twice the normal dose. However, there was no reported harm to the patients or users during these events. All incidents have been reported to CDRH.

IV. DEVICE DESCRIPTION

VALORY is a solid state x-ray system, a direct radiography (DR) system (product code MQB) intended to capture general radiographic images of the human body. VALORY is a ceiling mounted stationary X-Ray system with digital image capture that consists of a tube and operator console with a patient table and/or wall stand. VALORY uses Agfa's NX workstation with MUSICA² ™ image processing and flat-panel detectors of the scintillator-photodetector type (Cesium Iodide - CsI) to capture and process the digital image.

This submission is to add another ceiling-mount X-Ray system to Agfa's direct radiology portfolio.

The optional image processing allows users to conveniently select image processing settings for different patient sizes and examinations. The image processing algorithms in the subject device are identical to those previously cleared in the DR 600 (K152639) device and other devices in Agfa's radiography portfolio today.

Principles of operation and technological characteristics of the subject and predicate and devices are similar. There are no changes to the intended use/indications of the device. The new device is physically and electronically similar to the predicate device (K152639). It uses the same NX workstation with MUSICA™ image processing as the predicate device (K152639) and similar flat panel detectors of the scintillator-photodetector type (Cesium Iodide - CsI S) to capture and digitize the images as the predicate device (K152639).

Laboratory data and image quality evaluations conducted with internal specialists confirm that performance is equivalent to the predicates. Differences in devices do not alter the intended diagnostic effect nor do they impact the safety and effectiveness of the device.

Configuration information for the flat-panel detectors can be found in the respective user manuals. The Service Manual details the possible configurations and integrations with the NX workstation and X-ray generator. All of Agfa's DR X-ray systems (i.e. DX-D 100-K103597, DX-D 300-K103050, DX-D 600-K112670, DR 400-K141192, DR 600-K152639 (predicate), DR 800 with MUSICA Dynamic –K180589, DR 800 with Tomosynthesis – K183275, DR 100s – K191884 & DR 600 with Tomosynthesis – K193262) will integrate with the detectors. The NX3.x.23 Service Manual, Chapter 4 and associated appendices addresses the installation and configuration with other system components.

V. INDICATIONS FOR USE

The VALORY system is a General Radiography X-ray imaging system used in hospitals, clinics and medical practices by radiographers, radiologists and physicists to make, process and view static X-ray radiographic images of the skeleton (including skull, spinal column, and extremities), chest, abdomen, and other body parts on adults and pediatric patients.

Applications can be performed with the patient in sitting, standing or lying position.

The system is not intended for use in Mammography applications.

NOTE: The mammography applications embedded in the MUSICA software are for previously cleared CR imaging applications (K081963) and not intended for direct radiography (DR) imaging. Furthermore, the additional mammography software is only available through additional license

keys that must be purchased. These license keys are only available outside of the USA.

NOTE: DSA is not part of this submission; therefore, the functionality mentioned in the labeling documentation is out of scope for this clearance. DSA software is controlled using license keys and will not be accessible in this release of NX 23. Agfa submitted a 510(k) premarket notification for DSA on the DR 800 (K212145) and received clearance on August 31, 2021.

PEDIATRIC USE SUMMARY

VALORY is intended for general populations, including adult and pediatric patients of all ages. There are no specific pediatric and neonatal design features; however, VALORY provides the following specific design features and instructions that enable safer use of the device with pediatric and neonatal patients:

Pediatric Imaging Design Features	**Standard or Optional**
Protocols or exposure indices	Standard - make own exam tree optional - make use of age groups
Post-processing application	Standard
Reconstruction algorithm	Standard

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

The subject device and predicate device (K152639) are solid state imaging devices, Product Code MQB. VALORY is substantially equivalent to the predicate device (K152639) in that it uses the same basic technology to capture and transmit images. VALORY is a ceiling mounted stationary X-Ray system with digital image capture that consists of a tube and operator console with a patient table and/or wall stand. VALORY uses Agfa's NX workstation with MUSICA² ™ image processing and flat-panel detectors of the scintillator-photodetector type (Cesium Iodide - CsI) to capture and process the digital image.

Principles of operation and technological characteristics of the subject and predicate devices are similar. There are no changes to the intended use/indications of the device. The subject device is physically and electronically similar to the predicate device (K152639). It uses the same NX workstation with MUSICA™ image processing as the predicate device (K152639) and similar flat panel detectors of the scintillator-photodetector type (Cesium Iodide - CsI) to capture and digitize the images as the predicate device (K152639). Both the subject device and predicate device (K152639) are ceiling-mounted X-ray systems that consist of a tube and operator console with a patient table and/or wallstand.

The optional image processing allows users to conveniently select image processing settings for different patient sizes and examinations. The image processing algorithms in the subject device are similar to those previously cleared in the DR 600 (K152639) predicate device and other devices in Agfa's radiography portfolio today.

VALORY indications for use statement is substantially equivalent to the predicate device (K152639). The subject device and the predicate device (K152639) include the contraindication statement that the device is not indicated for mammography. The subject device and predicate device (K152639) have the same indications for use statements in that both devices are intended to display general radiographic images of the human body and include the delineation of anatomical areas and patient positions for imaging applications. Both devices are indicated for use in adult and pediatric patients.

The devices have the same technological characteristics. The minor differences between the subject device, VALORY, and predicate device (K152639) do not seem to impact safety or effectiveness.

Descriptive characteristics and performance data including image quality evaluations by qualified experts are adequate to ensure equivalence. Differences in devices do not alter the intended therapeutic/diagnostic effect. The table on the next page compares these technological characteristics.

PRODUCT COMPARISON TABLE			
	VALORY (Subject Device)	**DR 600 (PREDICATE – K152639)**	**Explanation of Differences**
Communications	Same as Predicate	DICOM	N/A
Detectors	Same as Predicate	CsI or GOS Flat Panel Detector(s)	N/A
Detector Sizes	Same as Predicate K152639	25x30cm, 35x43cm/ 14x17in, 43x43cm/ 17x17in	N/A
Operator Workstation	NX Workstations using Windows 7 & 10	NX Workstation using Windows 7	Addition of Windows 10
Image processing	MUSICA, MUSICA^2 MUSICA^3	MUSICA, MUSICA^2 MUSICA^3	Newer version of MUSICA since predicate clearance
Wallstand	Height: 235 cm Vertical Range: 35 cm to 200 cm Tilting Bucky: 0 º to $\pm$90º Radiation Absorb: <0.7mm Al equiv.	Height: 250 cm Vertical Range: 33.5 cm to 183 cm Tilting Bucky: -20º to $\pm$90º Radiation Absorb: <0.7mm Al equiv.	Minimal difference in height, range and tilting do not affect S/E.
Table	80x220.6 cm 53-82 cm height Max weight: 320 kg (705 lbs)	81x220 cm 55-90 cm height Max weight: 320 kg (705 lbs)	Minimal difference in width x length and height do not affect S/E.
AEC	Same as Predicate K152639	3-field ion chamber	N/A
Collimators	Same as Predicate K152639	Inherent Filtration: 2mm Al Add'l Filtration: -1mm Al + 0.1mm Cu, -1mm Al + 0.2mm Cu, -2mm Al FF Light Loc: > 160l x Rotation: 0º, $\pm$45º, $\pm$90º	N/A
Tubes	Same as Predicate K152639	Toshiba models: E7252X, E7254FX, E7869X, & E7884X	N/A
Ceiling-Mount X-Ray Tube Support	Max Vertical Travel: 1500 mm Rotation: $\pm$180º	Height: 2812 to 2965 mm Rotation: 0º, $\pm$90º, $\pm$12º, $\pm$180º	Shorter height but basically same rotation do not affect S/E
Generators	Same as Predicate K152639	Choice of three models: 50-80 KW	N/A
Power Supply	Same as Predicate K152639	50-60 Hz 380/400/415/440/480V $\pm$ 10%	N/A
Indications for Use	General Radiography X-Ray imaging system used in hospitals, clinics and medical practices by radiographers, radiologists and physicists to make, process and view static X-ray radiographic images of the skeleton (including skull, spinal column and extremities), chest, abdomen and other body parts on adults and pediatric patients. Applications can be performed with the patient in sitting, standing or lying position. Not intended for use in Mammography applications.	GenRad X-Ray imaging system used in hospitals, clinics and medical practices by radiographers, radiologists and physicists to make, process and view static X-ray radiographic images of the skeleton (including skull, spinal column and extremities), chest, abdomen and other body parts on adults and pediatric patients. Applications can be performed with the patient in sitting, standing or lying position. Not intended for use in Mammography applications.	No difference

VII. PERFORMANCE DATA

Laboratory testing and software testing (for a moderate level of concern device) using equivalent test protocols were evaluated by qualified individuals to demonstrate that adequate design controls (according to 21 CFR 820.30) were in place.

Verification and validation testing confirmed the device meets performance, safety, usability and security requirements. Pediatric indications were also taken into account. Results were verified and validated.

Clinical image quality evaluation is not essential in establishing substantial equivalence for VALORY. Adequate Bench Testing results should be sufficient to determine device safety and effectiveness.

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

Bench Testing

Image quality evaluations for adults and pediatric patients and usability data has been provided.

- Usability evaluations for VALORY were conducted with external radiographers. The usability studies evaluated overall product safety, including workflow functionality for adults and pediatric patients, system movements, information and support for components. The results of the usability tests, fulfillment of the validation acceptance criteria, and assessment of remaining defects support VALORY passing usability validation testing.

- Image quality validation testing was conducted using anthropomorphic adult and pediatric phantoms and evaluated by qualified internal experts and external radiographers. The radiographers evaluated the VALORY X-ray system with the DR 600 (predicate device, K152639) using XD 14 (K211790, pending 510(k) clearance) and DR 14s (K161368) flat-panel detectors comparing overall image quality. The test results indicated that the VALORY X-ray system has at least the same if not better image quality than the predicate device (DR 600 – K152639) and other flat-panel detectors currently on the market.

- Additional image quality validation testing for NX 23 was completed in scope of the DX-D Imaging Package with XD Detectors and included a full range of GenRad image processing applications compared to MUSICA 2 image processing using anonymized adult and pediatric phantoms and read by eight internal experts. The DX-D Imaging Package with XD Detectors is still pending 510(k) clearance, K211790). Please refer to that submission for all imaging quality validation documentation for NX 23, specifically.

Software Verification and Validation Testing

Verification and validation plans comprise of test protocols. The complete device has been certified and validated. During the final risk analysis meeting, the risk management team concluded that the medical risk is no greater than with conventional x-ray film previously released to the field.

Software verification testing for NX 23 was completed in scope of VALORY. MUSICA image processing was tested in relation to the Consolidated Requirements documented in **Exhibit 2-2** and linked to the Traceability Matrix **(Exhibit 3-6)**. HERDE defects were identified; however, they were solved between test execution and the completion of the final report and will be part of the next maintenance software release.

For the NX 23 (NX Orion) software there are a total of 535 risks in the broadly acceptable region and 37 risks in the ALARP region with only four of these risks identified. Zero risks were identified in the Not Acceptable Region. Therefore, the device is assumed to be safe, the benefits of the device are assumed to outweigh the residual risk. The software risk assessment is assessed on solution level for VALORY.

The term "Level of Concern" means the level of risk that the software device is determined to be if the software were to fail. The Level of Concern for VALORY and NX 23 has been determined to be moderate.

NOTE: DSA is not part of this submission; therefore, the functionality mentioned in the labeling documentation is out of scope for this clearance. DSA software is controlled using license keys and will not be accessible in this release of NX 23. Agfa submitted a 510(k) premarket notification for DSA on the DR 800 (K212145) and received clearance on August 31, 2021.

Electrical Safety and Electromagnetic Compatibility (EMC) Testing:

- IEC 60601-1: 2005 (2012) Medical Electrical Equipment: General Requirements for Basic Safety and Essential Performance.
- IEC 60601-1-2: 2015 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.
- IEC 60601-1-3: 2008 (2013) Medical Electrical Equipment – Part 1-3: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Radiation Protection in Diagnostic X-ray Equipment.
- IEC 60601-1-6: 2010 (2017) Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability.
- IEC 60601-2-28: 2010 (2017) Medical Electrical Equipment – Part 2-28: Particular Requirements for Basic Safety and Essential Performance of X-Ray Tube assemblies for medical diagnosis.
- IEC 60601-2-54: 2009 (2015) Medical Electrical Equipment – Part 2-54: Particular Requirements for Basic Safety and Essential Performance of X-Ray Equipment for Radiography and Radioscopy.

VALORY is compliant to FDA Subchapter J mandated performance standards 21 CFR 1020.30 and 1020.31.

Agfa's in-house standard operating procedures were also used for the development of the device and software; these procedures conform to the following standards:

- ISO 13485:2015 Medical Devices - Quality Management Systems
- ISO 14971:2012 Application of Risk Management to Medical Devices
- ACR/NEMA PS3.1-3.20: 2011 Digital Imaging and Communications in Medicine (DICOM)

- IEC 62366-1:2015 Medical Devices – Part 1: Application of Usability Engineering to Medical Devices
- IEC 62304:2006 Medical Device Software – Software Lifecycle Processes [Including Amendment 1 (2016)]

Guidance Documents

Agfa utilized the following guidance documents in the development of the VALORY:

- Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices (September 2016).
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 2005)
- Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software (Jan 2005)
- Off-the-Shelf Software Use in Medical Devices (September 2019)
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (Oct 2018)
- Guidance for Pediatric Information for X-ray Imaging Device Premarket Notifications (Nov 2017)

Summary

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

VIII. CONCLUSIONS

Agfa's VALORY system has indications for use that is consistent with that of the legally marketed predicate device (K152639). Intended uses are the same. Laboratory tests conclude that the device is substantially equivalent to the predicate. Differences in devices do not alter the intended diagnostic effect nor do they impact the safety and effectiveness of the device.

The subject device and DR 600 predicate device (K152639) are solid-state X-Ray Imagers, Product Code MQB. Agfa's VALORY system device is substantially equivalent to the predicate device (K152639) in that it uses the same basic technology to capture and transmit images.

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.