Agfa N.V.
% Mrs. ShaeAnn Cavanagh
Regulatory Affairs Manager, North America
Agfa US Corp.
10 South Academy Street
GREENVILLE SC 29601

July 30, 2021

Re: K211790
Trade/Device Name: DX-D Imaging Package with XD Detectors
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: June 9, 2021
Received: June 10, 2021

Dear Mrs. 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)*
K211790

Device Name
DX-D Imaging Package with XD Detectors

Indications for Use *(Describe)*
Agfa's DX-D Imaging Package with XD Detectors is indicated for use in general projection radiographic applications to capture for display diagnostic quality radiographic images of the human anatomy. The DX-D Imaging Package with XD Detectors may be used wherever conventional screen-film systems may be used.

Agfa's DX-D Imaging Package with XD Detectors s not indicated for use in mammography.

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 N.V.
DX-D Imaging Package with XD Detectors
K211790

I. SUBMITTER

Agfa N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Wim Govaerts, Prepared: June 9, 2021
Telephone: + 32 3444 6246

II. DEVICE

Name of Device: DX-D Imaging Package with XD Detectors

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 DX-D Imaging Package with XD Detectors which is a solid state x-ray system, a direct radiography (DR) system. It is substantially equivalent to Vieworks Co. Ltd's predicate device, Vivix-S VW (K200418) and Agfa's reference device, DX-D Imaging Package – DX-D 40 (K142184).

Predicate Device: Vivix-S VW
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

Reference Device: DX-D Imaging Package – DX-D 40
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

Neither the Vivix-S VW (K200418) predicate device nor the DX-D Imaging Package – DX-D 40 (K142184) reference device have not been subject to a design-related recall. However, several Agfa X-Ray systems that use the DX-D Imaging Package have identified "unintended movement" adverse events. Agfa has taken these reported defects into consideration and is mindful of these events while developing the subject device, DX-D Imaging Package with XD Detectors.

IV. DEVICE DESCRIPTION

The DX-D Imaging Package, previously cleared under K142184, 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. It is a combination of Agfa's NX workstation with MUSICA² ™ image processing and one or more flat-panel detectors of the scintillator-photodetector type (Cesium Iodide - CsI or Gadolinium Oxysulfide - GOS). It is capable of replacing other direct radiography, including computed radiography systems with conventional or phosphorous film cassettes.

This submission is to add the XD Detectors (XD 10/10+, XD 14/14+ and XD 17/17+) Flat Panel Detectors to Agfa's DX-D Imaging Package portfolio. Agfa's XD Detectors are currently marketed by Vieworks Co. Ltd. as FXRD-4343VAW/VAW Plus, FXRD-3643VAW/VAW Plus, and FXRD-2530VAW/VAW Plus which is the predicate for this submission (K200418).

The optional image processing allows users to conveniently select image processing settings for different patient sizes and examinations. The image processing algorithms in the new device are identical to those previously cleared in the DX-D Imaging Package – DX-D 40 (K142184-reference) device and other devices in Agfa's radiography portfolio today. The addition of the offline workflow is identical to the Vivix-S VW (K200418) predicate device.

Principles of operation and technological characteristics of the new, predicate and reference devices are the same. There are no changes to the intended use/indications of the device. The new device is physically and electronically similar to the predicate device (K200418) which includes the addition of an offline workflow capable of storing up to 200 images on the flat-panel detector for later viewing. It uses the same NX workstation with MUSICA™ image processing as the reference device (K142184) and the same flat panel detectors of the scintillator-photodetector type (Cesium Iodide - CsI or Gadolinium Oxysulfide - GOS) to capture and digitize the images as the predicate device (K200418). Laboratory data and image quality evaluations conducted with internal specialists confirm that performance is 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.

Performance characteristics between the subject device and reference device are summarized on the next page in tabular format.

Performance Characteristics	DX-D 40 Flat-Panel Detector (K142184)	DX-D 45 Flat-Panel Detector (K142184)	DX-D 60 Flat-Panel Detector (K142184)	XD 10/10+ Wireless Detector (new device)	XD 14/14+ Wireless Detector (new device)	XD 17/17+ Wireless Detector (new device)
Model	6007/100 & 6007/200	6007/101 & 6007/201	6007/110 & 6007/111	FXRD-2530VAW (PLUS)	FXRD-3643VAW (PLUS)	FXRD-4343VAW (PLUS)
Manufacturer	Vieworks Co. Ltd.	Vieworks Co. Ltd.	Vieworks Co. Ltd.	Vieworks Co. Ltd.	Vieworks Co. Ltd.	Vieworks Co. Ltd.
Spatial Resolution	3.5 lp/mm	4.0 lp/mm	3.5 lp/mm	4.0 lp/mm	3.5 lp/mm	3.5 lp/mm
DQE	**1 lp/mm –** CsI: 0.494 GOS: 0.259 **2 lp/mm –** CsI: 0.379 GOS: 0.157 **3lp/mm –** CsI: 0.215 GOS: 0.061	**1 lp/mm –** CsI: 0.524 GOS: 0.282 **2 lp/mm –** CsI: 0.450 GOS: 0.203 **3lp/mm –** CsI: 0.314 GOS: 0.118	**1 lp/mm –** CsI: 0.520 GOS: 0.294 **2 lp/mm –** CsI: 0.443 GOS: 0.212 **3lp/mm –** CsI: 0.301 GOS: 0.105	**1 lp/mm –** XD: 0.500 XD+: 0.587 **2 lp/mm –** XD: 0.401 XD+: 0.445 **3 lp/mm –** XD: 0.288 XD+: 0.316	**1 lp/mm –** XD: 0.425 XD+: 0.587 **2 lp/mm –** XD: 0.321 XD+: 0.399 **3 lp/mm –** XD: 0.206 XD+: 0.257	**1 lp/mm –** XD: 0.412 XD+: 0.587 **2 lp/mm –** XD: 0.345 XD+: 0.407 **3 lp/mm –** XD: 0.220 XD+: 0.280
MTF	**1 lp/mm –** CsI: 0.685 GOS: 0.589 **2 lp/mm –** CsI: 0.386 GOS: 0.266 **3lp/mm –** CsI: 0.209 GOS: 0.115	**1 lp/mm –** CsI: 0.685 GOS: 0.594 **2 lp/mm –** CsI: 0.383 GOS: 0.277 **3lp/mm –** CsI: 0.208 GOS: 0.129	**1 lp/mm –** CsI: 0.698 GOS: 0.588 **2 lp/mm –** CsI: 0.405 GOS: 0.272 **3lp/mm –** CsI: 0.224 GOS: 0.117	**1 lp/mm –** XD: 0.729 XD+: 0.650 **2 lp/mm –** XD: 0.424 XD+: 0.315 **3 lp/mm –** XD: 0.236 XD+: 0.157	**1 lp/mm –** XD: 0.751 XD+: 0.635 **2 lp/mm –** XD: 0.446 XD+: 0.302 **3 lp/mm –** XD: 0.247 XD+: 0.152	**1 lp/mm –** XD: 0.726 XD+: 0.656 **2 lp/mm –** XD: 0.428 XD+: 0.311 **3 lp/mm –** XD: 0.231 XD+: 0.161

Table 1: Detector Performance Characteristics

Configuration information for the flat-panel detectors can be found in the XD 10/10+, XD 14/14+, and XD 17/17+ (K200418) and DX-D 40/45/60 (K142184) User Manuals. The XD 10/10+, XD 14/14+, and XD 17/17+ detectors can be integrated in an X-ray system that communicates to a workstation. 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, DR 800-K183275) will integrate with the detectors.

V. INDICATIONS FOR USE

Agfa's DX-D Imaging Package with XD Detectors is indicated for use in general projection radiographic applications to capture for display diagnostic quality radiographic images of the human anatomy. The DX-D Imaging Package with XD Detectors may be used wherever conventional screen-film systems may be used.

Agfa's DX-D Imaging Package with XD Detectors is not indicated for use in mammography.

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 intends to submit a 510(k) premarket notification for DSA on the DR 800 later this year.

PEDIATRIC USE SUMMARY

The DX-D Imaging Package with XD Detectors is intended for general populations, including adult and pediatric patients of all ages. There are no specific pediatric and neonatal design features; however, the DX-D Imaging Package with XD Detectors 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

Table 2: Pediatric Design Features

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

The new device. predicate device (K200418) and the reference device (K142184) are solid state imaging devices, Product Code MQB. Agfa's DX-D Imaging Package with XD Detectors is substantially equivalent to both the predicate device (K200418) and the reference device (K142184) in that it uses the same basic technology to capture and transmit images.

Principles of operation and technological characteristics of the new, predicate and reference devices are the same. There are no changes to the intended use/indications of the device. The new device is physically and electronically similar to the predicate device (K200418) which includes the addition of an offline workflow capable of storing up to 200 images on the flat-panel detector for later viewing. It uses the same NX workstation with MUSICA™ image processing as the reference device (K142184) and the same flat panel detectors of the scintillator-photodetector type (Cesium Iodide - CsI or Gadolinium Oxysulfide - GOS) to capture and digitize the images as the predicate device (K200418). Differences in devices do not alter the intended diagnostic effect nor do they impact the safety and effectiveness of the device.

The optional image processing allows users to conveniently select image processing settings for different patient sizes and examinations. The image processing algorithms in the new device are identical to those previously cleared in the DX-D Imaging Package – DX-D 40 (K142184-reference) device and other devices in Agfa's radiography portfolio today. The addition of the offline workflow is identical to the Vivix-S VW (K200418) predicate device.

The DX-D Imaging Package with XD Detectors indications for use statement is substantially equivalent to both the predicate device (K200418) and the reference device (K142184). The new device and both the predicate device (K200418) and the reference device (K142184) include the statement that the device is not indicated for mammography The new device and both the predicate device (K200418) and the reference device (K142184) have similar indications for use statements in that both devices are intended to display general radiographic images of the human body and can be used in place of conventional film/screen systems. Intended uses are the same. The devices have the same technological characteristics.

The only difference between the new device and predicate device (K200418) Indication for Use statement is that the new device's Indication For Use statement includes specific references to the human body; however, standard practice dictates the predicate device is used for diagnostic procedures that include human anatomy. The differences between the subject device, DX-D Imaging Package with XD Detectors, predicate device K200418 and reference device K142184 do not seem to impact safety or effectiveness.

Performance data, image quality clinical evaluations, and usability/functionality data are adequate to ensure equivalence.

Similarities and differences between the subject device and predicate are summarized on the next page in tabular format.

PRODUCT COMPARISON TABLE			
	DX-D Imaging Package with XD Detectors (New Device)	**Vieworks – Vivix-S VW (PREDICATE – K200418)**	**Explanation of Differences**
Communications	Same as Predicate	Wireless/Wired	N/A
Flat Panel	Same as Predicate	Flat Panel Detector	N/A
Detector Material	Same as Predicate	Cesium Iodide (CsI) scintillator	N/A
Detector Sizes	Same as Predicate	25x30cm, 35x43cm/ 14x17in, 43x43cm/ 17x17in	N/A
Interface to Generator	Same as Predicate	AED & Synchronized	N/A
Pixel size	Same a Predicate	XD 10/10+ - 124 µm XD 14/14+ - 140 µm XD 17/17+ - 140 µm	N/A
Dynamic Range	Same as Predicate	16 bit	N/A
Power Supply	Same as Predicate	Battery: replaceable & rechargeable	N/A
Operator Workstation	NX Workstation	N/A, workstation is not included in the system	DX-D Imaging Package includes the NX workstation for image acquisition. The predicate device only includes the flat panel detector.
Image processing	MUSICA Imaging Processing	3rd Party Software	Agfa's proprietary image processing software
Indications for Use	Agfa's DX-D Imaging Package with XD Detectors is indicated for use in general projection radiographic applications to capture for display diagnostic quality radiographic images of human anatomy. The DX-D Imaging Package with XD Detectors may be used wherever conventional screen-film systems may be used. Agfa's DX-D Imaging Package with XD Detectors is not indicated for use in mammography.	The Vivix-S VW series is used for the general-purpose diagnostic procedures, as well as intended to replace radiographic film/ screen systems. The Vivix-S VW is not intended for mammography applications.	New device specifically references human anatomy, whereas the predicate device states general-purpose diagnostic procedures. However, standard practice dictates diagnostic procedures would include human anatomy.

Table 3: Device Comparison Table

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.

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, performance/functionality and usability data has been provided.

- Technical and acceptance testing was completed on the DR Retrofit and XD Detectors in order to confirm the medical device functions and performs as intended. All deviations or variances are documented in a defect database and addressed in the CRD documentation and verified. All mitigations have been tested and passed. All design input requirements have been tested and passed. All planned verification activities have been successfully completed.
- Performance functionality evaluations were conducted with four qualified experts. The results of these tests fell within the acceptance criteria for the DX-D Imaging Package with XD Detectors; therefore, the DX-D Imaging Package (DR Retrofit) supports XD Detectors and an offline workflow.

- Clinical image validation was conducted using anthropomorphic adult and pediatric phantoms and evaluated by qualified internal experts. The radiographers evaluated the DX-D Imaging Package with XD Detectors with DX-D 10/20 and DX-D 40/45/60 flat-panel detectors by comparing overall image quality. The image quality testing also validated MUSICA software of the imaging processing for general radiography (GenRad) applications for the DX-D Imaging Package with XD Detectors.

Clinical image quality evaluation is not essential in establishing substantial equivalence for the DX-D Imaging Package with XD Detectors. Adequate Bench Testing results should be sufficient to determine device safety and effectiveness.

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 the DX-D Imaging Package with XD Detectors. Two software iterations were tested, including the MUSICA image processing and VDI with the three XD Detectors (XD 10/10+, XD 14/14+, XD 17/17+). 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 the DX-D Imaging Package with XD Detectors (DR Retrofit).

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 the DX-D Imaging Package with XD Detectors 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 intends to submit a 510(k) premarket notification for DSA on the DR 800 later this year.

Electrical Safety and Electromagnetic Compatibility (EMC) Testing:

- IEC 60601-1: 2005 Medical Electrical Equipment: General Requirements for Safety and Essential Performance.
- IEC 60601-1-2: 2014 Medical Electrical Equipment – Part 1-2: General Requirements for Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.

The DX-D Imaging Package with XD Detectors do not fall under the scope of FDA Subchapter J mandated performance standards 21 CFR 1020.30 and 1020.31 since there is no risk of radiation leakage or change in radiation during the use of this device.

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 DX-D Imaging Package with XD Detectors:

- 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, the DX-D Imaging Package with XD Detectors is found to have a safety and effectiveness profile that is similar to the predicate device.

VIII. CONCLUSIONS

Agfa's DX-D Imaging Package with XD Detectors has indications for use that is consistent with that of the legally marketed predicate device (K200418) and reference device (K142184). 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 new device and the Vivix-S VW predicate device (K200418) and reference device, DX-D Imaging Package – DX-D 40 (K142184) are solid-state X-Ray Imagers, Product Code MQB. Agfa's DX-D Imaging Package with XD Detectors device is substantially equivalent to both the predicate device (K200418) and the reference device (K142184) 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.