DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 22, 2016

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

Re: K161368
Trade/Device Name: DX-D Imaging Package
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: August 26, 2016
Received: August 29, 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)*
K161368

Device Name

DX-D Imaging Package

Indications for Use *(Describe)*

Agfa's DX-D Imaging Package 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 may be used wherever conventional screen-film systems may be be used.

Agfa's DX-D Imaging Package is 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(K) SUMMARY
Agfa's DX-D Imaging Package – DR 10s & DR 14s Detectors

I. SUBMITTER

Agfa HealthCare N.V.
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Belgium

Contact: Koen Vervoort, Prepared: May 16, 2016
Telephone: +32-34444-7368

II. DEVICE

Name of Device: DX-D Imaging Package
Classification Name: Stationary X-Ray System
Regulatory Classification: Class II, 21 CFR 892.1680
Product Code: MQB

III. PREDICATE DEVICES

This is a 510(k) for Agfa's DX-D Imaging Package, a solid state, flat panel x-ray imaging device. It is substantially equivalent to Agfa's DX-D Imaging Package (K142184).

IV. DEVICE DESCRIPTION

Agfa's DX-D Imaging Package is a solid state flat panel x-ray system, a direct radiography (DR) system (product code MQB) intended to capture images of the human body. It is a combination of Agfa's NX workstation and one or more flat-panel detectors.

This submission is to add the DR10s and DR14s Flat Panel Detectors to Agfa's DX-D Imaging Package portfolio. The DX-D Imaging Package with the DR 10s and DR 14s wireless panels will be labeled as the Pixium 2430EZ and Pixium 3543EZ. DR 10s and DR 14s are commercial trade names used by Agfa HealthCare for marketing purposes only.

Principles of operation and technological characteristics of the new and predicate device are the same. There are no changes to the intended use/indications of the device. The new device is physically and electronically identical to the predicate, K142184. It uses the same workstation and the similar scintillator-photodetector flat panel detectors to capture and digitize the images as predicate K142184.

Laboratory data and image quality evaluations conducted with independent radiologists confirm that performance is equivalent to the predicate.

Performance Characteristics	DX-D 10 Flat-Panel Detector	DX-D 20 Flat-Panel Detector (Handle)	DX-D 40 Flat-Panel Instant Detector	DR 10s Wireless Detector	DR 14s Wireless Detector
Scintillator	CsI, GOS	CsI, GOS	CsI, GOS	CsI	CsI, GOS
Cassette size	35x43cm/14x17in	35x43cm/14x17in	35x43cm/14x17in	24x30cm	35x43cm/14x17in
Pixel Size	139 µm	139 µm	140 µm	148 µm	148 µm
A/D Conversion	14 bits	14 bits	14 bits	16 bits	16 bits
Interface to Generator	Ethernet	Ethernet	AED & Synchronized	AED & Synchronized	AED & Synchronized
Communication	Tethered	Tethered	Wireless	Wireless	Wireless
Power	I/O Interface Box: 100-240 VAC, 47-63 Hz	I/O Interface Box: 100-240 VAC, 47-63 Hz	Battery: replaceable & rechargeable	Battery: replaceable & rechargeable	Battery: replaceable & rechargeable
Weight	3.9 kg (8.6 lbs)	4.9 kg (10.8 lbs)	3.4 kg (7.5 lbs)	1.6 kg (3.53 lbs)	2.8 kg (6.17 lbs)
DQE	1lp/mm - 0.530/0.608; 2lp/mm - 0.219/0.298; 3lp/mm - 0.092/0.147	1lp/mm - 0.530/0.608; 2lp/mm - 0.219/0.298; 3lp/mm - 0.092/0.147	1lp/mm - 0..38/0.40; 2lp/mm - 0.23/0.24; 3lp/mm – 0.13/0.11	1lp/mm - 0.523: 2lp/mm - 0.476; 3lp/mm - 0.295	1lp/mm - 0.521/0.292; 2lp/mm - 0.449/0.189; 3lp/mm - 0.296/0.071
MTF	1lp/mm - 0.205/0.456; 2lp/mm - 0.106/0.304; 3lp/mm - 0.092/0.147	1lp/mm - 0.205/0.456; 2lp/mm - 0.106/0.304; 3lp/mm - 0.092/0.147	1lp/mm - 0.570/0.578; 2lp/mm – 0.269/0.279; 3lp/mm – 0.142/0.150	1lp/mm - 0.637: 2lp/mm - 0.360; 3lp/mm - 0.199	1lp/mm - 0.638/0.526; 2lp/mm - 0.363/0.208; 3lp/mm - 0.198/0.081

Configuration information can be found in the DR 10s and DR 14s User Manuals. The DR 10s and DR 14s detectors can be integrated in an X-ray system that communicates to a workstation. The DR 10s and DR 14s Service Manual details the possible configurations and integrations with the NX workstation and X-ray generator. All of Agfa HealthCare's DR and CR x-ray systems (i.e. DX-D 100-K103597, DX-D 300 –K103050, DX-D 600-K112670, DR 400-K141192, DR 600-K152639, CR 10-X-K121948, and CR 12-X-K131408) will integrate with the new device. The NX8900 Service Manual, Chapter 4 and associated appendices addresses the installation and configuration with other system components.

V. INDICATIONS FOR USE

Agfa's DX-D Imaging Package 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 may be used wherever conventional screen-film systems may be used.

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

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

VI. COMPARISON OF TEDCHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

Agfa's DX-D Imaging Package is a solid state flat panel x-ray system, a direct radiography (DR) system (product code MQB) intended to capture images of the human body. It is a combination of Agfa's NX workstation and one or more flat-panel detectors.

Principles of operation and technological characteristics of the new and predicate device are the same. There are no changes to the intended use/indications of the device. The new device is physically and electronically identical to the predicate, K142184. It uses the same workstation and the similar scintillator-photodetector flat panel detectors to capture and digitize the images as predicate K142184. There are no differences between the device and predicates K142184 that impact safety and effectiveness.

Performance data including laboratory image quality measurements (DQE), image quality clinical evaluations, and spatial frequency (MTF), grid test, and performance/functionality and usability data are adequate to ensure equivalence.

Agfa's DX-D Imaging Package has an Indications For Use statement identical to the predicate device (K142184). Intended uses are the same. The devices have the same technological characteristics.

The DX-D Imaging Package indications for use statement is substantially equivalent to the predicate device (K142184). The DX-D Imaging Package and predicate device (K142184) include the statement that the device is not indicated for mammography. The DX-D Imaging Package and predicate device (K142184) describe the imaging applications may be used utilized where screen-film systems exist. Differences in devices do not alter the intended diagnostic effect.

The table on the next page compares these technological characteristics.

PRODUCT COMPARISON TABLE		
	DX-D Img Pkg (New Device)	**AGFA DX-D Imaging Package (PREDICATE-K142184)**
Communications	Wireless	DICOM
Flat Panel	Same as Predicate	Flat Panel Detector
Detector Material	Same as Predicate	Gadolinium Oxysulfide (GOS) or Cesium Iodide (CsI) scintillator
Detector Sizes	10x12 in 14x17in	17x17 in. 14x17 in.
Active Matrix (14x17 in.)	2400 x 2880	2560 x 3072
Pixel size	148 μm	140 μm
Dynamic Range	16 bits	14 bit
Maximum Image Acquisitions/hr.	240	150
Power Supply	+12V 1A DC Battery	50-60 Hz 100-240V auto ranging
Operator Workstation	Same as Predicate	Agfa NX
Image processing	Same as Predicate	MUSICA
Operating system	Same as Predicate	Windows 7
Display System	Same as Predicate	Separately cleared medical display (K051901)
Indications for Use	Same as Predicate	Agfa's DX-D Imaging Package 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 may be used wherever conventional screen-film systems may be used. Agfa's DX-D Imaging Package is not indicated for use in mammography.

VII. PERFORMANCE DATA

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

Laboratory image quality measurements (DQE), image quality clinical evaluations, and spatial frequency (MTF), performance/functionality and usability data, and grid evaluation data have been provided.

In-hospital image quality comparisons have been conducted with qualified independent radiologists as well.

Where patient images were utilized, they were first anonymized to remove all identifying patient information. 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 measurement data (DQE), spatial frequency (MTF) data, performance/functionality data, usability data, and grid evaluation have been provided. No patient treatment was provided or withheld. No clinical or animal testing was performed in the development of the DX-D Imaging Package.

- Laboratory image quality (DQE) comparison and spatial frequency (MTF) evaluation of the DR 10sC, DR14sC, and DR14sG with other Agfa HealthCare flat-panel detectors currently on the market including the predicate (K142184). The test results confirmed that the DX-D Imaging Package with DR 10sC, DR14sC, and DR14sG flat-panel detectors was equivalent to other flat-panel detectors Agfa currently markets including the predicate (K142184).
- Usability and functionality evaluations were conducted with qualified independent radiographers. The results of these tests fell within the acceptance criteria for all of the flat-panel detectors; therefore, the DX-D Imaging Package supports a radiographic workflow including calibration, compatibility, linear dose and dynamic ranges, and sensitivity.
- Grid Evaluation was conducted with a qualified internal radiographer. The results of the grid evaluation of the chest, skull, and pelvis remained consistent with other Agfa HealthCare flat-panel detectors currently on the market including the predicate (K142184).. The intended use is fulfilled using different flat-panel detectors.
- Image Quality Validation testing was conducted using anthropomorphic phantoms and evaluated by qualified independent radiographers. The test results indicated that the DR 10sC, DR14sC, and DR14sG flat-panel detectors have at least the same if not better image quality than other flat-panel detectors currently on the market.

Software Validation Testing

Verification and validation plans comprise of test protocols. The software components of the device have 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.

For the DR 10s and DR 14s (XRDi17 software) there is only one risk identified in the Broadly Acceptable Region and no identified residual risks in the ALARP region after mitigation. 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.

There are no identified residual risks for the released NX software versions NX8900 (NX Juno) in the ALARP region after mitigation. Only one risk was identified in the Broadly Acceptable Region after mitigation. Therefore, the device is assumed to be safe, the benefits of the device are assumed to outweigh the residual risk.

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 NX 8900 device has been determined to be moderate and the Level of Concern for the XRDi17 software has been determined to be minor.

The product, manufacturing and development processes conform to product safety and medical imaging standards including:

PRODUCT STANDARDS

- IEC 60601-1: 2012 Medical Electrical Equipment: General Requirements for Safety and Essential Performance.
- IEC 60601-1-2: 2014-4 Medical Electrical Equipment - Part 1-2: General Requirements for Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.

QUALITY MANAGEMENT STANDARDS

- ISO 14971:2007 Application of Risk Management to Medical Devices
- ISO 13485:2003 Medical Devices - Quality Management Systems - Requirements For Regulatory purposes

Summary

Based on the performance data as documented in the above testing, DX-D Imaging Package is found to have a safety and effectiveness profile that is similar to the predicate devices.

VIII. GUIDANCE DOCUMENTS

The applicant is aware of the following guidance documents that apply to products of this type:

- Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices (August 1999).
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 2005).
- Off-the-Shelf Software Use in Medical Devices (September 1999).
- Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software (January 2005)
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (October 2014)

IX. CONCLUSIONS

Agfa's DX-D Imaging Package has an Indications For Use statement identical to the predicate device (K142184). Intended uses are the same. The devices have the same technological characteristics.

The DX-D Imaging Package indication for use is substantially equivalent to the predicate device

(K142184). The DX-D Imaging Package and predicate device (K142184) include the statement that the device is not indicated for mammography. The DX-D Imaging Package and predicate device (K142184) describe the imaging applications may be used utilized where screen-film systems exist. Differences in devices do not alter the intended diagnostic effect.

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

Principles of operation and technological characteristics of the new and predicate device are the same. There are no changes to the intended use/indications of the device. The new device is physically and electronically identical to the predicate, K142184. It uses the same workstation and the similar scintillator-photodetector flat panel detectors to capture and digitize the images as predicate K142184.

The DX-D Imaging Package with the DR 10s and DR 14s wireless panels will be labeled as the Pixium 2430EZ and Pixium 3543EZ. The DR 10s and DR 14s are commercial trade names used by Agfa HealthCare for marketing purposes only.

Performance data including laboratory image quality measurements (DQE), image quality clinical evaluations, and spatial frequency (MTF), grid test, and performance/functionality and usability data are adequate to ensure equivalence.

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.