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

October 13, 2017

Re: K172784
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: September 14, 2017
Received: September 15, 2017

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 (DICE) 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 (DICE) 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,

Michael D. O'Hara 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

4. Indications for Use Statement

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)*

K172784

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)*

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

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5. 510(K) Summary

510(K) SUMMARY
Agfa's DX-D Imaging Package – DR 14e & DR 17e Detectors

I. SUBMITTER

Agfa HealthCare N.V.
Septestraat 27
B-2640 Mortsel
Belgium

Contact: Wim Govaerts, Prepared: September 14, 2017
Telephone: +32-34444-6246

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 systems with Agfa's DX-D Imaging Package (K161368) and Innolux Corporation's Innolux RIC device (K162344).

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 general radiography 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 DR14e and DR17e Flat Panel Detectors to Agfa's DX-D Imaging Package portfolio. Agfa's DR 14e and DR 17e wireless panels are currently marketed by Innolux as RIC 35C/G and RIC 43C/G, which is one of the predicates for this submission.

Principles of operation and technological characteristics of the new and predicate devices are the same. There are no changes to the intended use/indications of the device. The new device is physically and electronically identical to both predicates, K161368 and K162344. It uses the same workstation as predicate K161368 and the same flat panel detectors to capture and digitize the images as predicate K162344.

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)	DR 14e Wireless Detector	DR 17e Wireless Detector
Scintillator	CsI, GOS	CsI, GOS	CsI, GOS	CsI, GOS
Cassette size	35x43cm/14x17in	35x43cm/14x17in	35x43cm/14x17in	43x43cm/17x17in
Pixel Size	139 µm	139 µm	150 µm	150 µm
A/D Conversion	14 bits	14 bits	16 bits	16 bits
Interface to Generator	Ethernet	Ethernet	AED & Synchronized	AED & Synchronized
Communication	Tethered	Tethered	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
Weight	3.9 kg (8.6 lbs)	4.9 kg (10.8 lbs)	2.95 kg (6.50 lbs)	3.65 kg (8.04 lbs)

Configuration information can be found in the DR 14e and DR 17e User Manuals. The DR 14e and DR 17e detectors can be integrated in an X-ray system that communicates to a workstation. The DR 14e and DR 17e Service Manual details the possible configurations and integrations with the NX workstation and X-ray generator. All of Agfa HealthCare's DR systems (i.e. DX-D 100-K103597, DX-D 300 –K103050, DX-D 600-K112670, DR 400-K141192, and DR 600-K152639) will integrate with the new device. The NX9000 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

The new device and the both predicate devices (K161368 & K162344) are solid state imaging devices, Product Code MQB. Agfa's DX-D Imaging Package is substantially equivalent to both predicate devices (K161368 and K162344) in that it uses precisely the same technology to capture and transmit images.

Principles of operation and technological characteristics of the new and predicate devices are the same. There are no changes to the intended use/indications of the device. The new device is physically and electronically identical to both predicates, K161368 and K162344. It uses the same workstation as predicate K161368 and the same flat panel detectors to capture and digitize the images as predicate K162344. Differences in devices do not alter the intended diagnostic effect.

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

The DX-D Imaging Package indications for use statement is substantially equivalent to both predicate devices (K161368 and K162344). The new device and both predicate devices (K161368 and K162344) include the statement that the device is not indicated for mammography. The DX-D Imaging Package and predicate device (K161368) describe the imaging applications may be used utilized where screen-film systems exist. The new device and predicate device (K162344) 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 or CR systems. Intended uses are the same. The devices have the same technological characteristics.

The only difference between the new device and predicate device (K162344) is that the predicate device's Indication For Use statement includes specific contraindications for fluoroscopy, angiography, and tomography. The specific contraindications are applicable to the new device since it is only indicated for general projection applications. Fluoroscopy, angiography and tomography are not considered to be general projection applications. There are no differences between the new device and predicates K161368 and K162344 that impact safety and effectiveness.

The table on the next page compares these technological characteristics.

PRODUCT COMPARISON TABLE			
	DX-D Imaging Package (New Device)	**AGFA DX-D Imaging Package (PREDICATE-K161368)**	**Innolux RIC (PREDICATE – K162344)**
Communications	Same as both Predicates	Wireless	Wireless/Wired
Flat Panel	Same as both Predicates	Flat Panel Detector	Flat Panel Detector
Detector Material	Same as both Predicates	Gadolinium Oxysulfide (GOS) or Cesium Iodide (CsI) scintillator	Gadolinium Oxysulfide (GOS) or Cesium Iodide (CsI) scintillator
Detector Sizes	Same as Predicate K162344	10x12 in. 14x17 in.	14x17 in 17x17in
Active Matrix	Same as Predicate K162344	2400 x 2880	2336x2836 2832x2836
Pixel size	Same a Predicate K162344	148 μm	150 μm
Dynamic Range	Same as both Predicates	16 bit	16 bit
Maximum Image Acquisitions/hr.	Same as Predicate K161368	240	--
Power Supply	Same as Predicate K162344	+12 V 1A DC Battery	6-12V 2.73A DC Battery
Operator Workstation	Same as Predicate K161368	Agfa NX	N/A, workstation is not included in the system
Image processing	Same as Predicate K161368	MUSICA	3rd Party Software
Operating system	Windows 7 & 10	Windows 7	Standard computer operating system
Display System	Same as Predicate K161368	Separately cleared medical display (K051901)	Separately cleared medical display
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.	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.	The INNOLUX RIC is intended to capture for display radiographic images of human anatomy. It is intended for use in general projection radiographic applications including pediatric and neonatal exams wherever conventional film/screen or CR systems may be used. RIC is not intended for mammography, fluoroscopy, tomography, and angiography applications.

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.

Performance data, image quality clinical evaluations, grid test, and usability/functionality 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 clinical evaluations, 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.

- Image Quality Validation testing was conducted using anthropomorphic phantoms and evaluated by qualified independent radiographers. The test results indicated that the DR 14e, and DR17e flat-panel detectors have at least the same if not better image quality than other flat-panel detectors currently on the market (DX-D 10 and DX-D 20).
- Usability and functionality evaluations were conducted with a qualified internal radiographer. 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.
- 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 (K161368). The intended use is fulfilled using different flat-panel detectors.

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.

The software components for the DR 14e and DR 17e comprise of the XRDi18 and NX9000 workstation. There are no risks identified in the Broadly Acceptable Region and no identified residual risks in the ALARP region after mitigation for XRDi18. 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 NX9000 in the ALARP region after mitigation. Only

three risks were 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 9000 device has been determined to be moderate and the Level of Concern for the XRDi18 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
- ISO 62366:2007 Application of Usability Engineering to Medical Devices
- ISO 62304:2006 Medical Device Software – Software Lifecycle Processes

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. CONCLUSIONS

Agfa's DX-D Imaging Package has an Indications For Use statement identical to the predicate devices (K161368 and K162344). Intended uses are virtually the same. The devices have the same technological characteristics.

The new device and the both predicate devices (K161368 & K162344) are solid state imaging devices, Product Code MQB. Agfa's DX-D Imaging Package is substantially equivalent to both predicate devices (K161368 and K162344) in that it uses precisely the same technology to capture and transmit images.

The DX-D Imaging Package indications for use statement is substantially equivalent to both predicate devices (K161368 and K162344). The new device and both predicate devices (K161368 and K162344) include the statement that the device is not indicated for mammography. The DX-D Imaging Package and predicate device (K161368) describe the imaging applications may be used

utilized where screen-film systems exist. The new device and predicate device (K162344) 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 or CR systems. Intended uses are the same. The devices have the same technological characteristics.

There are no differences between the device and predicates K161368 and K162344 that impact safety and effectiveness.

Performance data, image quality clinical evaluations, grid test, and usability/functionality 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.

10. Executive Summary

Reason for Submission

Agfa HealthCare is a manufacturer of a full line of analog and digital medical imaging devices. In 1990 it introduced its first computed radiography[2] system, the ADC 70. That device and each of its successor models used phosphor coated image plates to capture x-ray images, releasing the images upon exposure of the plates to a laser scanner (a digitizer). With these devices, images are previewed and manipulated on its NX computer workstation, and then sent to a printer or PACS system for use by the physician.

In 2009, Agfa introduced its first direct radiography[3] system, DX-D Imaging Package (K092669), which did not require a digitizer but captured images with scintillator flat panel detectors of Cesium Iodide or Gadolinium Oxysulfide manufactured for Agfa by Varian. Since then, Agfa has integrated its imaging package with traditional x-ray systems; for example, it's DX-D 100 (K103597), DX-D 300 (K103050) and DX-D 600 (K112670).

Agfa recently received premarket clearance for the DX-D40C/G Flat Panel Detector in the DX-D Imaging Package portfolio (K142184) in October 2014.

Agfa submitted a premarket notification to include the DR 10s and DR 14s Flat Panel Detectors in the DX-D Imaging Package portfolio (K161368) and received clearance in September 2016, which is one of the predicates for this submission.

Agfa is submitting this premarket notification because it plans to include the DR 14e and DR 17e Flat Panel Detectors in the DX-D Imaging Package portfolio. Agfa's DR 14e and DR 17e wireless panels are currently marketed by Innolux as RIC 35C/G and RIC 43C/G, which is one of the predicates for this submission.

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 general radiographic 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 devices are the same. There are no changes to the intended use/indications of the device. The new device is physically and electronically identical to both predicates, K161368 and K162344. It uses the same workstation as predicate K161368 and the same flat panel detectors to capture and digitize the images as predicate K162344. Differences in devices do not alter the intended diagnostic effect.

Agfa has tested the device to confirm it meets specifications and operates as planned. Performance data, image quality clinical evaluations, grid test, and usability/functionality data are adequate to ensure equivalence.

NOTE: The DX-D Imaging Package and its components are referred to by a number of names in

[2] Systems utilizing phosphor image plates are referred to as "computed radiography" (or CR) systems.
[3] Systems using photostimulable flat panel detectors are often referred to as "direct" or "digital radiography" (or DR) systems.

this submission and its exhibits: DX-D, DR, DR 14e, DR 17e. As used here, all these terms refer to the same device.

Required Information: (510(K) Summary, Integrity Statement, and Indications for Use)

The statement of Indications for Use is included as **Section 4**.

In accordance with 21 CFR 807.87(h), Agfa HealthCare NV has prepared a 510(k) Summary which is included as **Section 5**.

Also required by 21 CFR 807.87(k) is a statement certifying that the information contained in a 510(k) notification is truthful and accurate. This statement is included as **Section 6**.

Relevant Guidance

Agfa is aware of FDA guidance documents relevant to this submission. The influence of the following FDA documents is discussed briefly below:

- **Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices (August 1999).** The device is of the scintillator-photodetector type described in this guidance. The guidance requests certain imaging performance data for the imaging plate/digitizer system and flat-panel detectors. The detector used in the new device is identical to the detector in predicate (K161368). Test data is provided in **Section 18** and in the referenced **Exhibits 5 & 7**.

- **Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 2005).** This guidance requests manufacturers to assess the software "Level of Concern" and to provide certain information about the software. The software information presented in this submission is for the latest version of the NX workstation (NX9000). The software information is included in this submission in **Section 16**, and in the referenced exhibits.

- **Off-The-Shelf software Use in Medical Devices (September 1999).** FDA guidance for Off-the-Shelf Software asks device manufacturers consider carefully the risks imposed by use of off-the-shelf software and to provide certain basic information for the OTS software used in their devices. OTS software is included in the NX workstation. This information is provided in **Section 16**.

- **Cybersecurity of Networked Medical Devices Using Off-the-Shelf Software (January 2005).** FDA guidance raises concerns about cybersecurity threats of networked medical devices. Agfa addresses those concerns during development, manufacturing, installation and maintenance activities. OTS software is included in the NX workstation. Information is provided in **Section 16**.

- **Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (October 2014).** This guidance requires manufacturers to identify assets, threats, and vulnerabilities, to assess their likelihood and impact on device functionality and end users/patients, to determine risk levels and suitable mitigation strategies and to assess residual risk and risk acceptance criteria. **Section 16** provides information on how Agfa addressed item, functional and system level security including cyber-security for NX Workstation and DR 14e and DR 17e detectors.

Predicate Devices

The predicate devices are:

1. K161368 – Agfa's latest submission for the DX-D Imaging Package, and
2. K162344 – Innolux Corporation's Innolux RIC

The new device and the both predicate devices (K161368 & K162344) are solid state imaging devices, Product Code MQB. Agfa's DX-D Imaging Package is substantially equivalent to both predicate devices (K161368 and K162344) in that it uses precisely the same technology to capture and transmit images.

The DX-D Imaging Package indications for use statement is substantially equivalent to both predicate devices (K161368 and K162344). The new device and both predicate devices (K161368 and K162344) include the statement that the device is not indicated for mammography. The DX-D Imaging Package and predicate device (K161368) describe the imaging applications may be used utilized where screen-film systems exist. The new device and predicate device (K162344) 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 or CR systems. Intended uses are the same. The devices have the same technological characteristics.

The only difference between the new device and predicate device (K162344) is that the predicate device's Indication For Use statement includes specific contraindications for fluoroscopy, angiography, and tomography. The specific contraindications are applicable to the new device since it is only indicated for general projection applications. Fluoroscopy, angiography and tomography are not considered to be general projection applications. There are no differences between the new device and predicates K161368 and K162344 that impact safety and effectiveness.

Principles of operation and technological characteristics of the new and predicate devices are the same. There are no changes to the intended use/indications of the device. The new device is physically and electronically identical to both predicates, K161368 and K162344. It uses the same workstation as predicate K161368 and the same flat panel detectors to capture and digitize the images as predicate K162344. Differences in devices do not alter the intended diagnostic effect.

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

Testing Overview

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.

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

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.

- Image Quality Validation testing was conducted using anthropomorphic phantoms and evaluated by qualified independent radiographers. The test results indicated that the DR 14e, and DR17e flat-panel detectors have at least the same if not better image quality than other flat-panel detectors currently on the market (DX-D 10 and DX-D 20). Refer to **Exhibit 7** for the Image Quality Validation plan, report and completed scoresheets. Refer to **Exhibit 6** for Sample Images used in the image quality evaluations. **Section 18** contains the complete summary.

  MISC Files: Raw images are provided electronically on the eCopy CD-ROM.

- Usability and functionality evaluations were conducted with a qualified internal radiographer. 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. Refer to **Exhibit 5-2**, Design Verification Report, **Exhibit 5-4**, Design Validation Report and **Exhibit 5-7**, User Observation Sheet Report and **Section 18** for the results and referenced exhibits.

- 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 (K161368). The intended use is fulfilled using different flat-panel detectors. Refer to **Exhibit 5-8**, Grid Evaluation on IQ and **Section 18** for the complete results.

Device Description Overview

Section 11 of this submission, Device Description, contains a detailed description of Agfa's

DX-D Imaging Package. This section is intended as a brief introduction.

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 genral radiographic images of the human body. It is a combination of Agfa's **NX workstation** and one or more **flat-panel detectors**. It is integrated with compatible x-ray systems such as the DX-D 100 (K103597), DX-D 300 (K103050), DX-D 600 (K112670), DR 400 (K141192), and DR 600 (K152639).

Principles of operation and technological characteristics of the new and predicate devices are the same. There are no changes to the intended use/indications of the device. The new device is physically and electronically identical to both predicates, K161368 and K162344. It uses the same workstation as predicate K161368 and the same flat panel detectors to capture and digitize the images as predicate K162344. There are no differences between the device and predicates K161368 and K162344 that impact safety and effectiveness.

The **flat-panel Detector (DR 14e and DR 17e)** is used to capture the images. The have been cleared by the FDA and are used by a number of device manufacturers.

The detectors are identical to those used in the predicate, Innolux RIC flat panel detector (K162344). Detectors transmit the raw image to the NX workstation over a wired gigabit Ethernet connection or a wireless signal via an access point. They are provided in two sizes (a 17x17 in. and 14x17 in.), each with either a Cesium Iodide (CsI) or Gadolinium Oxysulfide (GOS) scintillator layer. The 17x17 in. detectors are used with fixed x-ray systems like the DX-D 600 (K112670) and DX-D 300 (K103050). The 14x17 in. detectors are provided with a handle for easy portability and are used with mobile x-ray systems like the DX-D 100 (K103597).

All of the detectors operate with the same underlying technology. X-rays are absorbed by the detector and converted to a raw digital data. That data is normalized, pixel-by-pixel before it is provided to the NX workstation for further processing and display. A real-time interpolation is also performed for any pixels identified as defective. **Table 2** on the following page summarizes this data:

Performance Characteristics	DX-D 10 Flat-Panel Detector	DX-D 20 Flat-Panel Detector (Handle)	DR 14e Wireless Detector	DR 17e Wireless Detector
Scintillator	CsI, GOS	CsI, GOS	CsI, GOS	CsI, GOS
Cassette size	35x43cm/14x17in	35x43cm/14x17in	35x43cm/14x17in	43x43cm/17x17in
Pixel Size	139 µm	139 µm	150 µm	150 µm
A/D Conversion	14 bits	14 bits	16 bits	16 bits
Interface to Generator	Ethernet	Ethernet	AED & Synchronized	AED & Synchronized
Communication	Tethered	Tethered	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
Weight	3.9 kg (8.6 lbs)	4.9 kg (10.8 lbs)	2.95 kg (6.50 lbs)	3.65 kg (8.04 lbs)

Table 2: Summary of Detector Performance Characteristics

The **NX Workstation** is a commercially available computer with Agfa software. All Agfa computed radiography and direct radiography systems us the NX workstation. The NX workstation is cleared under the following 510(k) premarket submissions; K053634 (NX1.0), K071162 (NX 2.X for MUSICA²), K081963 (NX2008 add MUSICA² Platinum), and K090672 (NX add neonatal and pediatric).

Workstations provide their users with these basic functions:

- Identify and select patients and exams from work lists,
- Match the digitized images with the appropriate patient and examination.
- Preview images and perform QC checks (e.g.: check if the patient moved during exposure, or confirm the exposure parameters used),
- Process images according to the exam type and other criteria,
- View images or send them to the appropriate location for viewing, printing and storage; be it a printer, a softcopy capable display such a Picture Archiving and Communications System (PACS) or an archive.
- When included as a component of an x-ray system; set and review patient exposure settings with a software x-ray console.
- When used with direct radiography systems, the workstation synchronizes the detectors with the x-ray system so that the exposure is not initiated until the detectors are ready.
- The ability to scan multiple images and stitch them together into a single image: Full Leg
- Full Spine.
- A full screen mode for utilizing the entire screen to display images.
- A configurable user interface button that makes it easy to call up third party applications,
- such as a RIS client, procedure book, etc.
- Enhanced security with the option to require a configurable ID before use.
- Configurable mandatory patient fields, for better data consistency.
- Support for departmental quality control efforts with the ability to export technical images
- to Agfa's user quality control tool, AUTO QC2 SP1. Multiple DICOM export destinations.
- The ability to print a study in its entirety by pressing the F7 key.

NX workstations are compatible with the complete line of Agfa direct radiography systems: DX-D Imaging Package, DX-D100, DX-D300, DX-D400, DR 400, DX-D 600, and DR 600. Users who have other Agfa DR systems can connect them to the NX workstation.

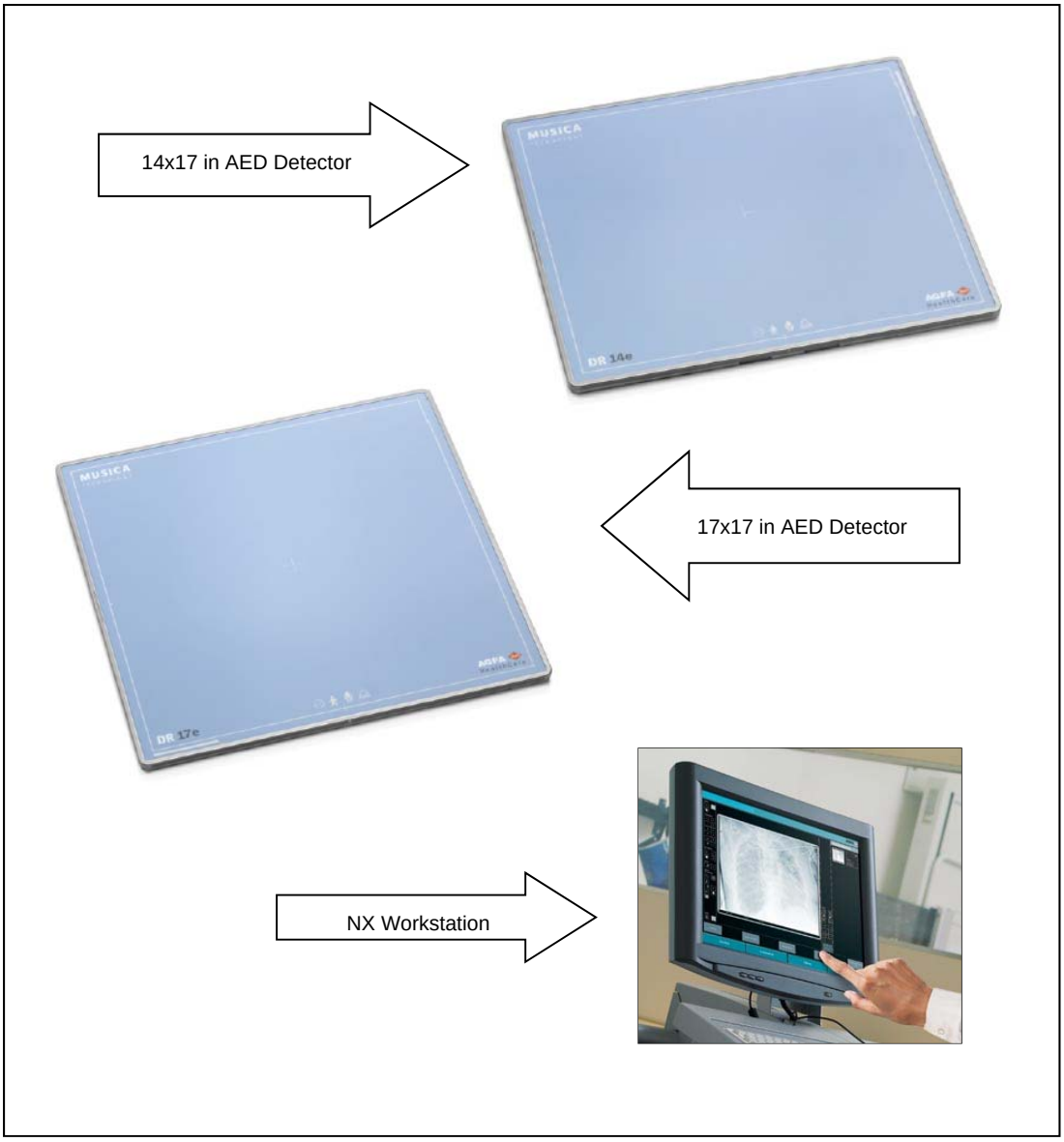

Figure 1: DX-D Imaging Package Components

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 of the DX-D Imaging Package, as described in the labeling, has not changed as a result of any labeling modification(s).

FDA Review Issues

Table 3 below summarizes the characteristics of the proposed device with respect to several FDA review issues.

510(k) Review Issues	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device implanted (short-term or long-term)?		X	
Does the device use software?	X		
Is the device shipped sterile?			X
Is the device single use?			X
Is the device home use?		X	
Is the device for prescription only?	X		
Does the device contain a drug or biological product as a component?		X	
Is this device a kit?		X	
Is the device subject to post-market surveillance		X	
Is the device subject to the Radiation Control Act	X		
Is a Class III Summary and Certification required?		X	
Is a financial certification or disclosure statement required?		X	

Table 3: 510(k) Review Issues

Regulatory History

Agfa digital radiography systems have been the subject of numerous 510(k) submissions. These are summarized in the **Table 4** below, beginning with the most recent:

Clearance	Change	Detector Model(s)
K161368	**DX-D Imaging Package**[4]	**DR 10s and DR 14s**
K152639	DR600	
K142184	DX-D Imaging Package	DX-D 40
K141602	DX-D Imaging Package	Dose Reduction indication
K141192	DR400	
K131408	CR 12-X	
K122736	DX-D Imaging Package	Pediatric/neonatal indication
K121095	DX-D Imaging Package	DX-D 30 (Wireless)
K121948	CR 10-X	
K112670	DX-D 600	
K111324	CR Mammography System with DX-M Digitizer	
K103597	DX-D 100	
K103050	DX-D 300	
K092669	**DX-D Imaging Package**[5]	**DX-D 10 & DX-D 20**
K092238	DX-G Digitizer	
K090672	NX Workstation (NX8000)	Pediatric/neonatal indication
K081963	NX Workstation (NX2008)	MUSICA² Platinum
K071162	NX 2.0 workstation	MUSICA²
K063421	DX-Si	
K062232	CR30-X	
K062742	CR85-X	
K053634	NX1.0 workstation	1st NX with MUSICA
Letter-to-file	QS workstation (QS version 3.0)	
K050810	DX-S (previously called CR50)	
Letter-to-file	QS workstation (QS version 2.1)	
K042779	Radiotherapy	
Letter-to-file	CR75	
K041701	CR25	
K021542	ADC Dental	
K012750	ADC Pediatric	
K013138	ADC Compact Plus	
K010571	ADC QS/IPD (workstation software, Uro/Tomo)	
K000159	Full Leg/Full Spine	
Letter-to-file	ADC Solo	
K974597	ADC Compact	
K904519	ADC 70	

Table 4: History of Agfa's Radiography 510(k) Submissions

[4] Predicate Device.

[5] Reference Device.

Initial Submission

The initial submission for Agfa's direct radiography (DR) systems was the DX-D Imaging Package (K092669). This submission is to add the DR14e and DR17e Flat Panel Detectors to Agfa's DX-D Imaging Package portfolio. Agfa's DR 14e and DR 17e wireless panels are currently marketed by Innolux as RIC 35C/G and RIC 43C/G, which is one of the predicates for this submission (K162344).

Substantial Equivalence Summary

This 510(k) will provide information that documents the path to substantial equivalence that is highlighted in the flowchart in **Section 12**. The detailed substantial equivalence argument is presented there.

The new device and the both predicate devices (K161368 & K162344) are solid state imaging devices, Product Code MQB. Agfa's DX-D Imaging Package is substantially equivalent to both predicate devices (K161368 and K162344) in that it uses precisely the same technology to capture and transmit images.

Principles of operation and technological characteristics of the new and predicate devices are the same. There are no changes to the intended use/indications of the device. The new device is physically and electronically identical to both predicates, K161368 and K162344. It uses the same workstation as predicate K161368 and the same flat panel detectors to capture and digitize the images as predicate K162344. Differences in devices do not alter the intended diagnostic effect.

The DX-D Imaging Package indications for use statement is substantially equivalent to both predicate devices (K161368 and K162344). The new device and both predicate devices (K161368 and K162344) include the statement that the device is not indicated for mammography. The DX-D Imaging Package and predicate device (K161368) describe the imaging applications may be used utilized where screen-film systems exist. The new device and predicate device (K162344) 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 or CR systems. Intended uses are the same. The devices have the same technological characteristics.

The only difference between the new device and predicate device (K162344) is that the predicate device's Indication For Use statement includes specific contraindications for fluoroscopy, angiography, and tomography. The specific contraindications are applicable to the new device since it is only indicated for general projection applications. Fluoroscopy, angiography and tomography are not considered to be general projection applications. There are no differences between the new device and predicates K161368 and K162344 that impact safety and effectiveness.

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

Table 5 on the next page summarizes the technical characteristics between the new device and the predicate devices (K161368 and K162344).

PRODUCT COMPARISON TABLE			
	DX-D Img Pkg (New Device)	**AGFA DX-D Imaging Package (PREDICATE-K161368)**	**Innolux RIC (PREDICATE – K162344)**
Communications	Same as both Predicates	Wireless	Wireless/Wired
Flat Panel	Same as both Predicates	Flat Panel Detector	Flat Panel Detector
Detector Material	Same as both Predicates	Gadolinium Oxysulfide (GOS) or Cesium Iodide (CsI) scintillator	Gadolinium Oxysulfide (GOS) or Cesium Iodide (CsI) scintillator
Detector Sizes	Same as Predicate K162344	10x12 in. 14x17 in.	14x17 in 17x17in
Active Matrix (14x17 in.)	Same as Predicate K162344	2400 x 2880	2336x2836 2832x2836
Pixel size	Same a Predicate K162344	148 µm	150 µm
Dynamic Range	Same as both Predicates	16 bit	16 bit
Maximum Image Acquisitions/hr.	Same as Predicate K161368	240	--
Power Supply	Same as Predicate K162344	+12 V 1A DC Battery	6-12V 2.73A DC Battery
Operator Workstation	Same as Predicate K161368	Agfa NX	N/A, workstation is not included in the system
Image processing	Same as Predicate K161368	MUSICA	3rd Party Software
Operating system	Windows 7 & 10	Windows 7	Standard computer operating system
Display System	Same as Predicate K161368	Separately cleared medical display (K051901)	Separately cleared medical display
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.	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.	The INNOLUX RIC is intended to capture for display radiographic images of human anatomy. It is intended for use in general projection radiographic applications including pediatric and neonatal exams wherever conventional film/screen or CR systems may be used. RIC is not intended for mammography, fluoroscopy, tomography, and angiography applications.

Table 5: Device Comparison Table

12. Substantial Equivalence Discussion

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.

The new device and the both predicate devices (K161368 & K162344) are solid state imaging devices, Product Code MQB. Agfa's DX-D Imaging Package is substantially equivalent to both predicate devices (K161368 and K162344) in that it uses precisely the same technology to capture and transmit images.

Principles of operation and technological characteristics of the new and predicate devices are the same. There are no changes to the intended use/indications of the device. The new device is physically and electronically identical to both predicates, K161368 and K162344. It uses the same workstation as predicate K161368 and the same flat panel detectors to capture and digitize the images as predicate K162344. Differences in devices do not alter the intended diagnostic effect.

The DX-D Imaging Package indications for use statement is substantially equivalent to both predicate devices (K161368 and K162344). The new device and both predicate devices (K161368 and K162344) include the statement that the device is not indicated for mammography. The DX-D Imaging Package and predicate device (K161368) describe the imaging applications may be used utilized where screen-film systems exist. The new device and predicate device (K162344) 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 or CR systems. Intended uses are the same. The devices have the same technological characteristics.

The only difference between the new device and predicate device (K162344) is that the predicate device's Indication For Use statement includes specific contraindications for fluoroscopy, angiography, and tomography. The specific contraindications are applicable to the new device since it is only indicated for general projection applications. Fluoroscopy, angiography and tomography are not considered to be general projection applications. There are no differences between the new device and predicates K161368 and K162344 that impact safety and effectiveness.

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

Figure 3 on the next page illustrates the decision of substantial equivalence for Agfa's DX-D Imaging Package.

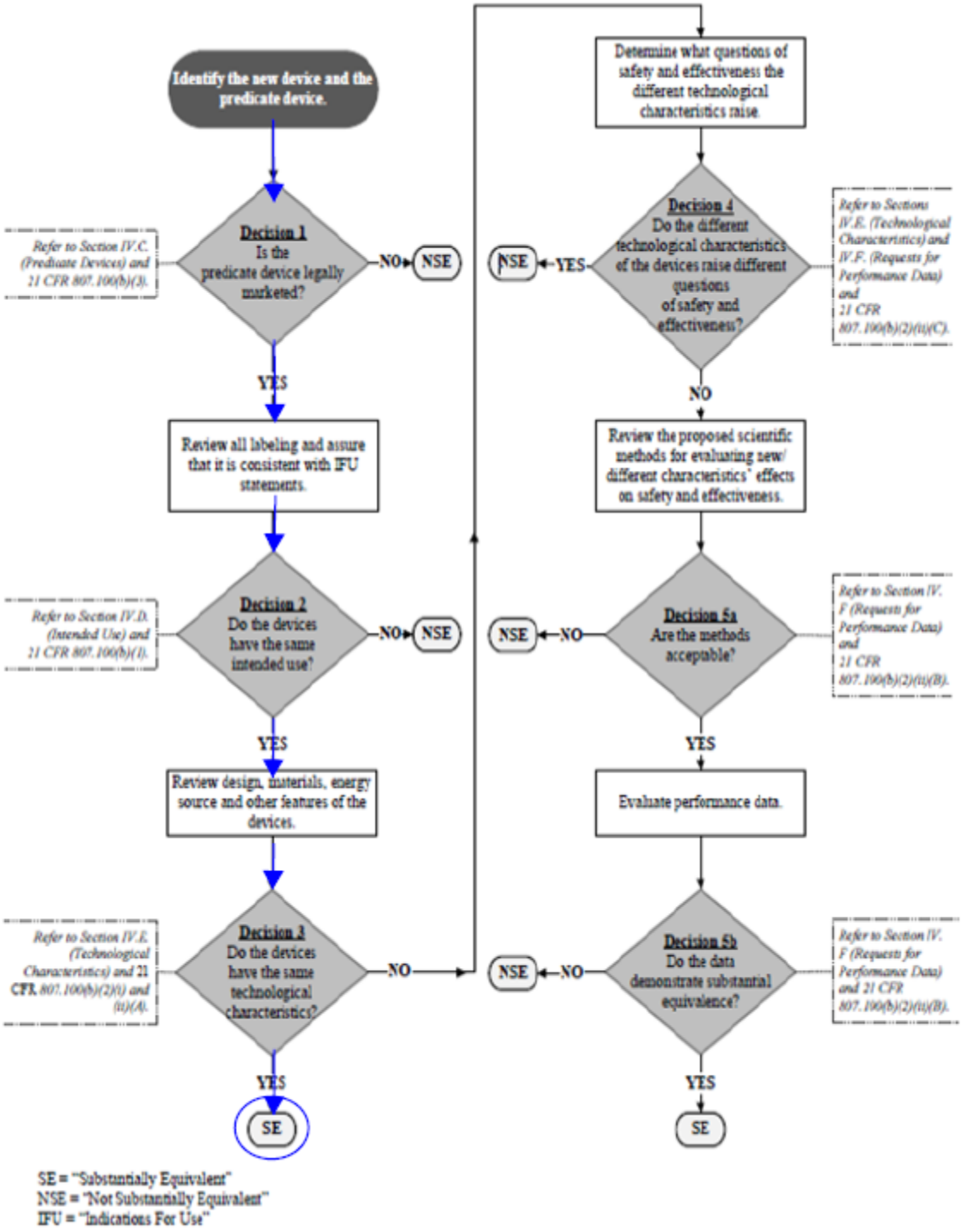

Figure 3: 510(K) Decision Making Process

Predicate Devices

The predicate devices are Agfa's DX-D Imaging Package (K161368) and Innolux Corporation's Innolux RIC system (K162344). Agfa recently received premarket clearance to include the DR 10s and DR 14s Flat Panel Detector in the DX-D Imaging Package portfolio (K161368) which is one of the predicates for this submission.

The new device and the both predicate devices (K161368 & K162344) are solid state imaging devices, Product Code MQB. Agfa's DX-D Imaging Package is substantially equivalent to both predicate devices (K161368 and K162344) in that it uses precisely the same technology to capture and transmit images.

Laboratory testing and independent image evaluations support these claims.

Substantial Equivalence

The Substantial Equivalence Algorithm is illustrated in the figure above.

Is the predicate device legally marketed?

Yes. This is the 510(k) for Agfa's DX-D Imaging Package to add the DR 14e and DR 17e Detectors to Agfa's portfolio. Agfa's DR 14e and DR 17e wireless panels are currently marketed by Innolux as RIC 35C/G and RIC 43C/G, which is one of the predicates for this submission (K162344).

Agfa's DX-D Imaging Package (K161368) has been legally on the market since September 2016 and has not been subject to a design-related recall. The software for NX 9000 (NX Kepler) is being submitted to the FDA as part of this 510(k) submission and is a minor modification of the NX 8900 (NX Juno) which was submitted to the FDA as part of the DR 600 510(k) documentation (K152639) and has been legally on the market since January 2017. The NX 9000 has not been subject to a design-related recall.

Do the Devices Have the Same Intended Use?

Yes. The wordings of the indications statements are similar. There are no changes in the intended therapeutic of diagnostic effects of the DX-D Imaging Package.

Agfa's DX-D Imaging Package indications for use statement is substantially equivalent to both predicate devices (K161368 and K162344). The new device and both predicate devices (K161368 and K162344) include the statement that the device is not indicated for mammography. The DX-D Imaging Package and predicate device (K161368) describe the imaging applications may be used utilized where screen-film systems exist. The new device and predicate device (K162344) 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 or CR systems. Intended uses are the same. The devices have the same technological characteristics.

The only difference between the new device and predicate device (K162344) is that the predicate device's Indication For Use statement includes specific contraindications for fluoroscopy, angiography, and tomography. The specific contraindications are applicable to the new device

since it is only indicated for general projection applications. Fluoroscopy, angiography and tomography are not considered to be general projection applications. There are no differences between the new device and predicates K161368 and K162344 that impact safety and effectiveness.

Do the Devices Have the Same Technological Characteristics?

Yes. The new device and the both predicate devices (K161368 & K162344) are solid state imaging devices, Product Code MQB. Agfa's DX-D Imaging Package is substantially equivalent to both predicate devices (K161368 and K162344) in that it uses precisely the same technology to capture and transmit images.

Predicate K161368 The DX-D Imaging Package is physically and electronically similar to the new device. It uses flat panel detectors to capture and digitize the image and uses the NX Workstation with MUSICA for image processing.

Predicate K162344 The Innolux RIC system is physically and electronically identical to the new device. It uses flat panel detectors to capture and digitize the image. Innolux RIC 35 C/G and 43C/G flat panel detectors are currently marketed by Innolux Corporation.

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

Image quality validation confirmed the new device is equal to or better than other Agfa detectors currently on the market, including the predicates (K161368 and K162344). This is confirmed by image quality tests described in **Section 18** and referenced in **Exhibits 5 & 7.**

See **Table 7** on the following page for a comparison of technical characteristics.

Do different technological characteristics of devices raise different questions of safety & effectiveness?

Not applicable, Substantial Equivalence is achieved by answers in decision points 1 through 3.

Agfa believes the descriptive characteristics are sufficiently precise to assure substantial equivalence. Performance data, image quality clinical evaluations, grid test, and usability/functionality data has been provided in **Section 18** and in the referenced Exhibits. A side-by-side comparison of the descriptive characteristics of the new and predicate devices is presented in **Table 7** on page 12-6.

Are the methods acceptable?

Not applicable, Substantial Equivalence is achieved by answers in decision points 1 through 3.

Agfa believes these tests represent acceptable methodologies. Performance data, image quality clinical evaluations, grid test, and usability/functionality data confirmed the new device is equal to or better than other Agfa detectors currently on the market, including the predicate devices (K161368 and K162344).

Does the Data Demonstrate Substantial Equivalence?

Not applicable, Substantial Equivalence is achieved by answers in decision points 1 through 3.

The performance data included in **Section 18** and the referenced Exhibits demonstrate that the DX-D Imaging Package is equivalent to its predicate devices (K161368 and K162344).

Substantial Equivalence

The decision algorithm brings us to a determination of Substantial Equivalence as defined in the Federal Food, Drug, and Cosmetic Act.

Comparison of Descriptive Characteristics

Table 7 on the following page provides a side-by side comparison of the characteristics of new and predicate devices.

PRODUCT COMPARISON TABLE			
	DX-D Img Pkg (New Device)	**AGFA DX-D Imaging Package (PREDICATE-K161368)**	**Innolux RIC (PREDICATE – K162344)**
Communications	Same as both Predicates	Wireless	Wireless/Wired
Flat Panel	Same as both Predicates	Flat Panel Detector	Flat Panel Detector
Detector Material	Same as both Predicates	Gadolinium Oxysulfide (GOS) or Cesium Iodide (CsI) scintillator	Gadolinium Oxysulfide (GOS) or Cesium Iodide (CsI) scintillator
Detector Sizes	Same as Predicate K162344	10x12 in. 14x17 in.	14x17 in 17x17in
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Pixel size	Same a Predicate K162344	148 μm	150 μm
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Power Supply	Same as Predicate K162344	+12 V 1A DC Battery	6-12V 2.73A DC Battery
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Image processing	Same as Predicate K161368	MUSICA	3rd Party Software
Operating system	Windows 7 & 10	Windows 7	Standard computer operating system
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Table 7: Device Comparison Table