



Food and Drug Administration
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Agfa HealthCare N.V.
% Ms. ShaeAnn Cavanagh
Premarket Regulatory Affairs Manager, NA
AGFA HealthCare Corp.
10 South Academy Street
GREENVILLE SC 29601

December 11, 2015

Re: K152639
Trade/Device Name: DR 600
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: November 23, 2015
Received: November 24, 2015

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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style with a light grey shadow effect behind the text.

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)

K152639

Device Name

DR 600

Indications for Use (Describe)

The DR 600 is a GenRad X-ray imaging system used in hospitals, clinics and medical practices by radiographers, radiologists and physicists to make, process and view static X-ray radiographic images of the skeleton (including skull, spinal column and extremities), chest, abdomen and other body parts on adults and pediatric patients. Applications can be performed with the patient in sitting, standing or lying position.

The DR 600 is not intended for use in Mammography applications.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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 Digital Radiography (DR) Systems with DR 600

I. SUBMITTER

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

Contact: Koen Vervoort, Prepared: September 14, 2015
Telephone: +32-34444-7368

II. DEVICE

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

III. PREDICATE DEVICES

This is a 510(k) for Agfa's DR 600, a solid state x-ray imaging device. It is substantially equivalent to systems with Agfa's DX-D 600 (K112670) and DR 400 (K141192).

These predicates have not been subject to a design-related recall. No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

Agfa's DR 600 is a solid state x-ray system, a direct radiography (DR) system (product code MQB) intended to capture images of the human body. The device is a combination of a conventional x-ray system with digital image capture. The DR 600 is a ceiling mounted tube and operator console with a motorized patient table and/or wall stand. The DR 600 uses Agfa's NX workstation with MUSICA²™ image processing and flat-panel detectors of the scintillator-photodetector type (Cesium Iodide - CsI or Gadolinium Oxysulfide - GOS). It is compatible with Agfa's computed radiography systems as well.

This submission is to add the DR 600 to Agfa's direct radiology portfolio.

Principles of operation and technological characteristics of the new and predicate devices are the same. The new device is physically and electronically identical to the predicate K112670 and virtually identical to predicate K141192 with the exception that it has a ceiling mounted tube instead of floor mounted tube. It uses the same workstation and similar scintillator-photodetector

flat panel detectors to capture and digitize the image.

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 used in the predicates (K141192 & K112670).

Detectors

DR 600 includes the option of using one of three detectors; DX-D 10, DX-D 20, and DX-D 40. Each of these detectors are flat-panel scintillator-photodetectors (size 43x 35cm/ 14x17in) with a choice of either Cesium Iodide (CsI) or Gadolinium Oxy-Sulphide (GOS) detector conversion screens. The DX-D 10 and DX-D 20 detectors are both tethered; however, the DX-D 20 detector has a handle. The DX-D 40 detector is an instant detector with automatic exposure detection (AED) and wireless technology. A table further explaining the detector performance characteristics is on the next page.

Performance Characteristics	DX-D 10 Flat-Panel Detector	DX-D 20 Flat-Panel Detector (Handle)	DX-D 40 Flat-Panel Instant Detector
Scintillator	CsI, GOS	CsI, GOS	CsI, GOS
Cassette size	35x43cm/14x17in	35x43cm/14x17in	35x43cm/14x17in
Pixel Size	139 µm	139 µm	140 µm
Nyquist Frequency	3.6 lp/mm	3.6 lp/mm	3.6 lp/mm
A/D Conversion	14 bits	14 bits	14 bits
Interface to Generator	Ethernet	Ethernet	AED & Synchronized
Communication	Tethered	Tethered	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
Weight	3.9 kg (8.6 lbs)	4.9 kg (10.8 lbs)	3.4 kg (7.5 lbs)
DQE (G/C)	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
MTF (G/C)	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

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

V. INDICATIONS FOR USE

The DR 600 is a GenRad X-ray imaging system used in hospitals, clinics and medical practices by radiographers, radiologists and physicists to make, process and view static X-ray radiographic images of the skeleton (including skull, spinal column and extremities), chest, abdomen and other body parts on adults and pediatric patients. Applications can be performed with the patient in sitting, standing or lying position.

The DR 600 is not intended for use in Mammography applications.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

Agfa's DR 600 The new device and the DR 400 predicate device (K141192) are solid state imaging devices, Product Code MQB. Agfa's DR 600 is substantially equivalent to both predicate devices (K141192 & K112670) in that it uses precisely the same technology to capture and transmit images. The new device is a combination of a conventional x-ray system with digital image capture. The DR 600 is a ceiling mounted tube and operator console with a motorized patient table and/or wall stand. The DR 600 uses the same NX workstation with MUSICA²™ image processing and flat-panel detectors of the scintillator-photodetector type (Cesium Iodide - CsI or Gadolinium Oxysulfide - GOS) as both predicates (K141192 & K112670). It is compatible with Agfa's computed radiography systems as well.

Principles of operation and technological characteristics of the new and predicate devices are the same. The new device is physically and electronically identical to the predicate K112670 and virtually identical to predicate K141192 with the exception that it has a ceiling mounted tube instead of floor mounted tube. It uses the same workstation and similar scintillator-photodetector flat panel detectors to capture and digitize the image.

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 used in the predicates (K141192 & K112670).

Performance data including laboratory image quality measurements and image comparison studies by independent radiologists are adequate to ensure equivalence.

Agfa's DR 600 has an Indications For Use statement identical to both predicate devices (K141192 & K112670). Intended uses are the same. The devices have the same technological characteristics.

The DR 600 indications for use is equivalent to predicates (K141192 & K112670) because all three include the delineation of anatomical areas and patient positions for the imaging applications. The DR 600 and predicate devices (K141192 & K112670) include the statement that the device is not indicated for mammography; however, predicate K112670 is not indicated for pediatric and neonatal patient populations. Differences in devices do not alter the intended diagnostic effect.

The table on the next page compares these technological characteristics.

	DR 600 (New Device)	DR 400 (PREDICATE –K141192)	AGFA DX-D 600 (PREDICATE-K112670)
Communications	Same as predicates	DICOM	DICOM
Flat Panel or Image Plate	Same as predicates	Flat Panel Detector	Flat Panel Detector
Detector Material	Same as predicates	Gadolinium Oxysulfide (GOS) or Cesium Iodide (CsI) scintillator	Gadolinium Oxysulfide (GOS) or Cesium Iodide (CsI) scintillator
Detector Sizes	14x17 in.	17x17 in. 14x17 in.	17x17 in. 14x17 in.
Active Matrix (14x17 in.)	Same as predicate K112670	2560 x 3072	2560 x 3072 3070 x 3072
Pixel size	Same as predicates	139 µm	139 µm
Dynamic Range	Same as predicates	14 bit	14 bit DR, 12 bit CR
Maximum Image Acquisitions/hr.	Same as predicates	150	150
Power Supply	Same as predicate K112670	50-60 Hz 100-240V auto ranging	50-60 Hz 380/400/415/440/480V ± 10%
Operator Workstation	Same as predicates	Agfa NX	Agfa NX
Image processing	Same as predicates	MUSICA, MUSICA ²	MUSICA ²
Generators	Choice of three models: 50-80 KW	Choice of four models: 40-80 KW	Choice of four models: 32-80 KW
Tubes	Same as predicates	Toshiba models: E7252X, E7254FX, E7869X, & E7884X	Toshiba models: E7252X, E7254FX, E7869X, & E7884X
Operating system	Same as predicate K141192	Windows 7	Windows XP Pro
Display System	Same as predicates	Separately cleared medical display (K051901)	Separately cleared medical display (K051901)
Indications for Use Statements	DR 600 system is a GenRad X-Ray imaging system used in hospitals, clinics and medical practices by physicians, radiographers and radiologists to make, process, and view static X-Ray radiographic images of the skeleton (including skull, spinal column and extremities), chest, abdomen and other body parts on adult and pediatric patients. Applications can be performed with the patient in the sitting, standing or lying position. DR 600 is not indicated for use in mammography	DR 400 system is a GenRad X-Ray imaging system used in hospitals, clinics and medical practices by physicians, radiographers and radiologists to make, process, and view static X-Ray radiographic images of the skeleton (including skull, spinal column and extremities), chest, abdomen and other body parts on adult and pediatric patients. Applications can be performed with the patient in the sitting, standing or lying position. DR 400 is not indicated for use in mammography	DX-D 600 system is indicated to make static X-Ray radiographic images of the skeleton (including skull, spinal column and extremities), chest, abdomen and other body parts. Applications can be performed with the patient in the sitting, standing or lying position. This device is not intended 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 and imaging plates was evaluated by qualified individuals employed by the sponsor to demonstrate that adequate design controls (according to 21 CFR 820.30) were in place.

The following performance data are provided in support of the substantial equivalence determination.

Bench Testing

Image quality measurement data, performance/functionality data, grid tests, and usability data has been provided. No patient treatment was provided or withheld. No clinical or animal testing was performed in the development of the DR 600.

- Laboratory image quality comparison of the DR 600 and DR 400 (predicate K141192) and DX-M (CR System) anthropomorphic phantoms were performed in pairs by the qualified independent radiologists. There were no artifacts detected using the DR 600 system that could influence image quality. Both systems used MUSICA for image processing on the NX workstation. The study confirmed that the Agfa DR 600 system with the flat-panel detector and CR cassettes and plates was equivalent to or better in performance than the DR 400 and DX-M.
- Usability and functionality evaluations were conducted with qualified independent radiographers. The study evaluated Agfa's DR 600 system regarding design, functionality, and usability within a hospital environment. The results of the usability test fell within the acceptance criteria for all components; therefore, the DR 600 supports a radiographic workflow. The usability and functionality of Full Leg Full Spine (FLFS) workflow for DR was rated positive as well. The intended use is fulfilled using different flat-panel detectors.
- Grid Tests were conducted with a qualified internal radiographer. The study evaluated flat field, chest and skull phantoms created using all grids defined for the DR 600 system. The results of the grid tests remained consistent with the DR 400 (predicate K141192) results. The Varian (DX-D 10) and Vieworks (DX-D 40) detectors worked well and had positive results. The intended use is fulfilled using different flat-panel detectors and/or CR cassettes and plates.

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.

For the DR 600 there are a total of 97 risks in the broadly acceptable region and eight risks in the ALARP region. 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 21 residual risks in the ALARP region for the released NX software versions NX8900 (NX Juno) are not greater than the risks of a conventional x-ray machine. The 81 risks identified in the Broadly Acceptable Region are in zone A and B. Therefore, the device is regarded as safe and the benefits of the device 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 device has been determined to be moderate.

Electrical Safety and Electromagnetic Compatibility (EMC) Testing:

- ACR/NEMA PS3.1-3.20: 2011 Digital Imaging and Communications in Medicine (DICOM).
- IEC 60601-1: 2012 Medical Electrical Equipment: General Requirements for Safety and Essential Performance.
- IEC 60601-1-2: 2007 Medical Electrical Equipment - Part 1-2: General Requirements for Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.
- IEC 60601-1-3: 2008 Medical Electrical Equipment - Part 1-3: General Requirements for Safety and Essential Performance - Collateral Standard: Radiation Protection in Diagnostic X-Ray Equipment
- IEC 60601-2-28: 2010 Medical Electrical Equipment – Part 2-28: Particular Requirements for the Basic Safety and Essential Performance of X-Ray Tube Assemblies for Medical Diagnosis.
- IEC 60601-2-54: 2009 Medical Electrical Equipment – Part 2-54: Particular Requirements for the Basic Safety and Essential Performance of X-Ray Equipment for Radiography and Radioscopy.
- ISO 14971:2012 Application of Risk Management to Medical Devices
- ISO 13485:2012 Medical Devices - Quality Management Systems - Requirements For Regulatory purposes

Summary

Based on the performance data as documented in the above testing, the DR 600 is found to have a safety and effectiveness profile that is similar to the predicate devices.

VIII. CONCLUSIONS

Agfa’s DR 600 has an Indications For Use statement identical to both predicate devices (K141192 & K112670). Intended uses are the same. The devices have the same technological characteristics.

The DR 600 indications for use is equivalent to predicates (K141192 & K112670) because all three include the delineation of anatomical areas and patient positions for the imaging applications. The DR 600 and predicate devices (K141192 & K112670) include the statement that the device is not indicated for mammography; however, predicate K112670 is not indicated for pediatric and neonatal patient populations. Differences in devices do not alter the intended diagnostic effect.

The new device and the DR 400 predicate device (K141192) are solid state imaging devices,

Product Code MQB. Agfa's DR 600 is substantially equivalent to both predicate devices (K141192 & K112670) in that it uses precisely the same technology to capture and transmit images.

There are no changes to the intended use/indications of the device. The DR 600 uses the same NX workstation and similar detectors as both predicates (K141192 & K112670).

Differences in devices do not alter the intended diagnostic effect. Performance data including laboratory image quality measurements and image comparison studies by independent radiologists 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.