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

March 9, 2020

Re: K193262
Trade/Device Name: DR 600 with Tomosynthesis
Regulation Number: 21 CFR 892.1740
Regulation Name: Tomographic x-ray system
Regulatory Class: Class II
Product Code: IZF, MQB
Dated: February 7, 2020
Received: February 10, 2020

Dear Ms. Cavanagh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193262

Device Name
DR 600 with Tomosynthesis

Indications for Use *(Describe)*

The DR 600 system is a General Radiography X-ray imaging system used in hospitals, clinics and medical practices by radiographers, radiologists and physicists to make, process and view static X-ray radiographic images of the skeleton (including skull, spinal column and extremities), chest, abdomen and other body parts on adult, pediatric or neonatal patients.

In addition, the system provides the Agfa tomosynthesis option, which is intended to acquire tomographic slices of human anatomy and to be used with Agfa DR X-ray systems. Digital tomosynthesis is used to synthesize tomographic slices from a single tomographic sweep.

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

This system is not intended for mammography applications.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

Agfa N.V.
DR 600 with Tomosynthesis

I. SUBMITTER

Agfa N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Wim Govaerts, Prepared: November 26, 2019
Telephone: + 32 3444 6246

II. DEVICE

Name of Device: DR 600 with Tomosynthesis

Common Name: System, X-Ray, Tomographic
Classification Name: Tomographic X-ray System
Regulatory Classification: Class II, 21 CFR 892.1740
Product Code: IZF

III. PREDICATE DEVICES

This is a 510(k) for Agfa's DR 600 with Tomosynthesis which is a tomographic and solid state x-ray system. It is substantially equivalent to both of Agfa's predicate devices, DR 800 with Tomosynthesis (primary - K183275) and DR 600 (K152639).

Primary Predicate Device: DR 800 with Tomosynthesis
Common Name: System, X-Ray, Tomographic
Classification Name: Tomographic X-ray System
Regulatory Classification: Class II, 21 CFR 892.1740
Product Code: IZF

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

Neither the DR 800 with Tomosynthesis (K183275) primary predicate device nor the DR 600 (K152639) predicate device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The DR 600 with Tomosynthesis is a tomographic and solid state x-ray system (product codes IZF and MQB) intended to capture tomographic slices and static images of the human body. The DR 600 with Tomosynthesis is a ceiling mounted tomographic and general radiographic system that consists of a tube and operator console with a motorized patient table and/or wall stand. The DR 600 with Tomosynthesis 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 capable of replacing other direct radiography, tomography, image intensifying tubes and TV cameras, including computed radiography systems with conventional or phosphorous film cassettes.

This submission is to add the newest version of the DR 600 with Tomosynthesis to Agfa's radiography portfolio.

The optional image processing allows users to conveniently select image processing settings for different patient sizes and examinations. The image processing algorithms in the new device are identical to those previously cleared in the DR 800 (K183275- primary) and DR 600 (K152639) predicate devices and other devices in Agfa's radiography portfolio today. The addition of the tomographic image processing is identical to the DR 800 (K183275) primary predicate device.

Principles of operation and technological characteristics of the new and predicate devices are the same. The new device is virtually identical to Agfa's predicate DR 600 (K152639) with the exception that it has additional MUSICA Digital TomoSynthesis (DTS) software for processing tomographic slices. MUSICA DTS software is identical to the software in Agfa's predicate DR 800 with Tomosynthesis (K183275). It uses the same flat panel detectors to capture and digitize the image. Laboratory data and image quality evaluations conducted with internal and independent specialists confirm that performance is equivalent to the predicates. Differences in devices do not alter the intended diagnostic effect nor do they impact the safety and effectiveness of the device.

Configuration information for the flat-panel detectors can be found in the DR 14s (K161368), DR 14e/17e (K172784), DX-D 40/45/60 (K142184) and DR 600 User Manuals. The DR 14s, DR 14e/17e, RF FL4343 and DX-D 40/45/60 detectors can be integrated in an X-ray system that communicates to a workstation. The Service Manual details the possible configurations and integrations with the NX workstation and X-ray generator. All of Agfa's DR X-ray systems (i.e. DX-D 100-K103597, DX-D 300-K103050, DX-D 600-K112670, DR 400-K141192, DR 600-K152639, DR 800-K183275) will integrate with the detectors. The NX Service Manual, Chapter 4 and associated appendices addresses the installation and configuration with other system components.

V. INDICATIONS FOR USE

The DR 600 system is a General Radiography X-ray imaging system used in hospitals, clinics and medical practices by radiographers, radiologists and physicists to make, process and view static X-ray radiographic images of the skeleton (including skull, spinal column and extremities), chest, abdomen and other body parts on adult, pediatric or neonatal patients.

In addition, the system provides the Agfa tomosynthesis option, which is intended to acquire tomographic slices of human anatomy and to be used with Agfa DR X-ray systems. Digital tomosynthesis is used to synthesize tomographic slices from a single tomographic sweep.

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

This system is not intended for mammography applications.

NOTE: The mammography applications embedded in the MUSICA software are for previously cleared CR imaging applications (K081963) and not intended for direct radiography (DR) imaging. Furthermore, the additional mammography software is only available through additional license keys that must be purchased. These license keys are only available outside of the USA.

PEDIATRIC USE SUMMARY

The DR 600 with Tomosynthesis is intended for general populations, including adult and pediatric patients of all ages. There are no specific pediatric and neonatal design features; however, the DR 600 with Tomosynthesis provides the following specific design features and instructions that enable safer use of the device with pediatric and neonatal patients:

Pediatric Imaging Design Features	**Standard or Optional**
Protocols or exposure indices	Standard - make own exam tree optional - make use of age groups
Filter and removable grid	Standard
Collimator alignment	Standard
Variable focal spot size	Standard
Post-processing application	Standard/ no specific pediatric post processing for tomo
Reconstruction algorithm	no specific pediatric reconstruction algorithm

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

Agfa's DR 600 with Tomosynthesis and the DR 800 with Tomosynthesis primary predicate device (K183275) are tomographic x-ray systems, Product Code IZF. The new device and DR 600 predicate device (K152639) are solid state x-ray systems, Product Code MQB). Agfa's DR 600 with Tomosynthesis is substantially equivalent to both predicate devices (K183275 & K152639) in that it uses precisely the same technology to capture and transmit images. The complete DR 600 system consists of a stationary table, ceiling mounted suspension equipped with a collimator and tube housing assembly, integrated x-ray generator, NX MUSICA software and one or more DR flat-panel detectors.

Principles of operation and technological characteristics of the new and predicate devices are the same. The new device is virtually identical to Agfa's predicate DR 600 (K152639) with the exception that it has additional MUSICA Digital TomoSynthesis (DTS) software for processing tomographic slices. MUSICA DTS software is identical to the software in Agfa's predicate DR 800 with Tomosynthesis (K183275). It uses the same flat panel detectors to capture and digitize the image. Laboratory data and image quality evaluations conducted with internal and independent specialists confirm that performance is equivalent to the predicates. Differences in devices do not alter the intended diagnostic effect nor do they impact the safety and effectiveness of the device.

The optional image processing allows users to conveniently select image processing settings for different patient sizes and examinations. The image processing algorithms in the new device are identical to those previously cleared in the DR 800 (K183275- primary) and DR 600 (K152639) predicate devices and other devices in Agfa's radiography portfolio today. The addition of the tomographic image processing is identical to the DR 800 (K183275) primary predicate device.

Agfa's DR 600 with Tomosynthesis has an Indications For Use statement virtually identical to predicate device (K152639) except it includes the addition of tomosynthesis. However, the tomosynthesis addition is identical to the statement in primary predicate device (K183275). Intended uses are the same. The devices have the same technological characteristics.

The DR 600 with Tomosynthesis indications for use is equivalent to predicate (K152639) because both include the delineation of anatomical areas and primary predicate (K183275) includes imaging applications and the application of tomosynthesis. The DR 600 with Tomosythnesis and both predicate devices (K183275 and K152639) include the statement that the devices are not indicated for mammography.

The new device and the DR 800 with Tomosynthesis primary predicate device (K183275) are tomographic x-ray systems, Product Code IZF. The new device and DR 600 predicate device (K152639) are solid state x-ray systems, Product Code MQB). Agfa's DR 600 with Tomosynthesis is substantially equivalent to both predicate devices (K183275 & K152639) in that it uses precisely the same technology to capture and transmit images.

Descriptive characteristics and performance data including image quality evaluations by internal and external specialists are adequate to ensure equivalence.

Table 2 on the next page summarizes the similarities and differences between the new device and predicates.

	DR 600 with Tomosynthesis (NEW DEVICE)	DR 800 with Tomosynthesis (PRIMARY PREDICATE) K183275	DR 600 (PREDICATE) K152639
Communications	Same as both predicate	DICOM	DICOM
Flat Panel Detectors	Same as both predicates	Flat Panel Detectors	Flat Panel Detectors
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 both predicates	17x17 in. 14 x 17 in 10 x 10 in	14 x 17 in
Pixel Size	Same as both predicates	148 µm	139 µm
Dynamic Range	Same as both predicates	16 bit	14 bit
Operator Workstation	Same as both predicates	Agfa NX	Agfa NX
Image processing	MUSICA DTS MUSICA^2 MUSICA3/3+	MUSICA Dynamic MUSICA DTS MUSICA^2 MUSICA3/3+	MUSICA^2
Operating System	Same as predicate K183275	Windows 7, 8, 8.1, 10	Windows XP Pro
Display System	Same as both predicates	Separately cleared medical display (K051901)	Separately cleared medical display (K051901)
Power Supply	Same as predicate K152639	50-60 Hz 100-240V auto ranging	50-60 Hz 380/400/415/440/480V $\pm$ 10%
Generators	Same as predicate K183275	Choice of three models: 50, 65KW, 80 KW	Choice of four models: 32-80 KW
Indications for Use Statements	The DR 600 system is a General Radiography X-ray imaging system used in hospitals, clinics and medical practices by radiographers, radiologists and physicists to make, process and view static X-ray radiographic images of the skeleton (including skull, spinal column and extremities), chest, abdomen and other body parts on adult, pediatric or neonatal patients. In addition, the system provides the Agfa tomosynthesis option, which is intended to acquire tomographic slices of human anatomy and to be used with Agfa DR X-ray systems. Digital tomosynthesis is used to synthesize tomographic slices from a single tomographic sweep. Applications can be performed with the patient in the sitting, standing or lying position. This device is not intended for mammography applications.	The DR 800 system is indicated for performing dynamic imaging examinations (fluoroscopy and/or rapid sequence) of the following anatomies/procedures: Positioning fluoroscopy procedures, Gastro-intestinal examinations, Urogenital tract examinations, and Angiography. It is intended to replace fluoroscopic images obtained through intensifier technology. In addition, the system is intended for project radiography of all body parts. In addition, the system provides the Agfa Tomosynthesis option, which is intended to acquire tomographic slices of human anatomy and to be used with Agfa DR X-ray systems. Tomosyntheis is used to synthesize tomographic slices from a single tomographic sweep. The DR 800 is not intended for mammography applications.	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 perfomed with the patient in the sitting, standing or lying position. DR 600 is not indicated for use in mammography.

Table 1: Device Comparison Table

VII. PERFORMANCE DATA

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

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

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

Bench Testing

Image quality evaluations for adults and pediatric patients, performance/functionality and usability data has been provided.

- Technical and acceptance testing was completed on the DR 600 in order to confirm the medical device functions and performs as intended. All deviations or variances are documented in a defect database and addressed in the CRD documentation and verified. All mitigations have been tested and passed. All design input requirements have been tested and passed. All planned verification activities have been successfully completed.
- Usability and functionality evaluations were conducted with three qualified radiographers. The results of these tests fell within the acceptance criteria for the DR 600; therefore, the DR 600 supports a tomographic workflow and Smart Dr visualization including adult and pediatric patients.
- Clinical image validation was conducted during testing in support for the 510(k) clearance for the flat-panel detectors (K161368, K172784 and K142184) in a previous premarket submission. Refer to these 510(k) clearances for full image quality validation testing for the detectors. Image quality bench tests were conducted in support of this 510(k) submission in which anthropomorphic adult and pediatric images taken with the DR 600 and the primary predicate device, DR 800 (K183275) were compared to ensure substantial equivalency. The test results indicated the image processing of the DR 600 passed the acceptance criteria and was equal to the image processing for the primary predicate, DR 800 (K183275) device for both adult and pediatric patients

Performance data including clinical image quality evaluations for adults and pediatric patients, performance/functionality and usability data are adequate to ensure equivalence.

Software Verification and Validation Testing

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

Software verification testing for Digital TomoSynthesis (DTS) was completed in scope of the DR 600 system. Four software iterations were tested, including the tube head and XRDi. HERDE defects were identified; however, they were solved between test execution and the completion of the final report and will be part of the next maintenance software release.

For the NX22 (NX Nomad) software there are a total of 342 risks in the broadly acceptable region and 27 risks in the ALARP region with only one of these risks identified. Zero risks were identified in the Not Acceptable Region. Therefore, the device is assumed to be safe, the benefits of the device are assumed to outweigh the residual risk. The software risk assessment is assessed on solution level for the DR 600 and also includes separate risk assessments for the NX 22 software and XRDi.

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 DR 600 with Tomosynthesis and NX 22 has been determined to be moderate.

Electrical Safety and Electromagnetic Compatibility (EMC) Testing:

- IEC 60601-1: 2012 Medical Electrical Equipment: General Requirements for Safety and Essential Performance.
- IEC 60601-1-2: 2014 Medical Electrical Equipment – Part 1-2: General Requirements for Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.
- 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 60601-1-6: 2010 Medical Electrical Equipment – Part 1-6: General Requirements for Safety and Essential Performance – Collateral Standard Usability
- IEC 60601-2-28: 2010 Medical Electrical Equipment – Part 2-28 Particular Requirements for 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.

The DR 600 with Tomosynthesis is compliant to the FDA Subchapter J mandated performance standard 21 CFR 1020.30 and 1020.31.

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

- ISO 13485:2015 Medical Devices - Quality Management Systems
- ISO 14971:2012 Application of Risk Management to Medical Devices

- ACR/NEMA PS3.1-3.20: 2011 Digital Imaging and Communications in Medicine (DICOM)

Guidance Documents

Agfa utilized the following guidance documents in the development of the DR 600 with Tomosynthesis:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 2005)
- Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software (January 2005)
- Off-the-Shelf Software Use in Medical Devices (September 2019)
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (October 2018)
- Guidance for Pediatric Information for X-ray Imaging Device Premarket Notifications (November 2017)

Summary

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

VIII. CONCLUSIONS

Agfa's DR 600 with Tomosynthesis has indications for use that is consistent with that of the legally marketed predicate devices (K183275 & K152639). Intended uses are the same. Laboratory tests conclude that the device is substantially equivalent to the predicates. Differences in devices do not alter the intended diagnostic effect nor do they impact the safety and effectiveness of the device.

The new device and the DR 800 with Tomosynthesis primary predicate device (K183275) are tomographic x-ray systems, Product Code IZF. The new device and DR 600 predicate device (K152639) are solid state x-ray systems, Product Code MQB). Agfa's DR 600 with Tomosynthesis is substantially equivalent to both predicate devices (K183275 & K152639) in that it uses precisely the same technology to capture and transmit images.

This 510(k) has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.