February 1, 2019

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

Re: K183275
Trade/Device Name: DR 800 with Tomosynthesis
Regulation Number: 21 CFR 892.1740
Regulation Name: Tomographic x-ray system
Regulatory Class: Class II
Product Code: IZF, JAA
Dated: November 20, 2018
Received: November 23, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183275

Device Name

DR 800 with Tomosynthesis

Indications for Use *(Describe)*

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
• Angiography

It is intended to replace fluoroscopic images obtained through image 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. Tomosynthesis is used to synthesize tomographic slices from a single tomographic sweep.

The DR 800 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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5. 510(K) Summary

510(K) SUMMARY

Agfa N.V.
DR 800 with Tomosynthesis

I. SUBMITTER

Agfa N.V.
Septestraat 27
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Belgium
Contact: Wim Govaerts, Prepared: November 20, 2018
Telephone: + 32 3444 6246

II. DEVICE

Name of 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

Common Name: System, X-Ray, Fluoroscopic Image-Intensified
Classification Name: Fluoroscopic X-ray System
Regulatory Classification: Class II, 21 CFR 892.1650
Product Code: JAA

III. PREDICATE DEVICES

This is a 510(k) for Agfa's DR 800, which is tomographic and fluoroscopic x-ray system. It is substantially equivalent to GE Medical System's Discover XR656 with VolumeRAD (K132261) and Agfa's previous version of the DR 800 with MUSICA Dynamic (K180589).

Primary Predicate:
Name of Device: Discover XR656 with VolumeRAD
Common Name: System, X-Ray, Tomographic
Classification Name: Tomographic X-ray System
Regulatory Classification: Class II, 21 CFR 892.1740
Product Code: IZF

Reference Predicate:
Name of Device: DR 800 with MUSICA Dynamic
Common Name: System, X-Ray, Fluoroscopic, Image-Intensified
Classification Name: Fluoroscopic X-ray System
Regulatory Classification: Class II, 21 CFR 892.1650
Product Code: JAA

The DR 800 with MUSICA Dynamic (K180589) predicate has not been subject to a design-related recall.

The Discovery XR656 with VolumeRAD (K132261) primary predicate device was part of a Class II recall initiated on 8/20/2014 and terminated by CDRH on 2/20/2015. The recall was for nylon hooks used to support the FlashPad detector on the wall stand. No injuries were reported.

IV. DEVICE DESCRIPTION

Agfa's DR 800 with Tomosynthesis a tomographic and fluoroscopic x-ray system (product codes IZF and JAA) intended to capture tomographic slices of the human body. The DR 800 is a floor-mounted radiographic, fluoroscopic and tomographic system that consists of a tube and operator console with a motorized tilting patient table and bucky with optional wall stand, FLFS overlay and ceiling suspension. The new device uses Agfa's NX workstation with MUSICA image processing and flat-panel detectors for digital and wide dynamic range image capture. 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 800 with Tomosynthesis to Agfa's radiography portfolio.

The image processing algorithms in the new device are similar to those previously cleared in the DR 800 with MUSICA Dynamic (K180589) and other devices in Agfa's radiography portfolio today which includes DR 600 (K152639) and DR 400 (K141192). The addition of the tomographic image processing is similar to the predicate device (K132261).

Principles of operation and technological characteristics of the new and predicate devices are the same. The new device is virtually identical to Agfa's DR 800 with MUSICA Dynamic (K180589) with the exception that it has additional MUSICA Digital TomoSynthesis (DTS) software for processing tomographic slices. The Discovery XR656 with VolumeRAD (K132261) contains similar software for processing tomographic slices of human anatomy. It uses the same flat panel detectors to capture and digitize the image. 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.

Configuration information for the flat-panel detectors can be found in the DR 14s (K161368) and DR 800 (K180589) User Manuals. The DR 14s and RF FL4343 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 with MUSICA Dynamic –K180589) will integrate with the detectors. The NX4.x.21 Service Manual, Chapter 4 and associated appendices addresses the installation and configuration with other system components.

V. INDICATIONS FOR USE

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
- Angiography

It is intended to replace fluoroscopic images obtained through image 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. Tomosynthesis is used to synthesize tomographic slices from a single tomographic sweep.

The DR 800 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), fluoroscopic or tomosynthesis 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 800 is intended for general populations, including adult and pediatric patients of all ages. Specific design features of the DR 800 for pediatric use include but not limited to using the specific AEC values, NX protocol settings per pediatric age range and automatic brightness control with pediatric settings to lower the dose for pediatric fluoroscopic applications.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

Agfa's DR 800 with Tomosynthesis and GE Medical System's Discovery XR656 with VolumeRAD primary predicate device (K132261) are tomographic x-ray imaging devices, Product Code IZF. The DR 800 with Tomosynthesis also has product code JAA which is identical the Agfa DR 800 with MUSICA Dymanic predicate device (K180589). Agfa's DR 800 is substantially equivalent to the primary predicate device (K132261) in that it uses precisely the same technology to capture and transmit images. The DR 800 is a floor-mounted radiographic, fluoroscopic and tomographic system that consists of a tube and operator console with a motorized tilting patient table and bucky with optional wall stand, FLFS overlay and ceiling suspension. The new device uses Agfa's NX workstation with MUSICA image processing and flat-panel detectors for digital and wide dynamic range image capture. 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.

Principles of operation and technological characteristics of the new and predicate devices are the same. The new device is virtually identical to Agfa's DR 800 with MUSICA Dynamic (K180589) with the exception that it has additional MUSICA DTS software for processing tomographic slices. The Discovery XR656 with VolumeRAD (K132261) contains similar software for processing tomographic slices of human anatomy. It uses the same flat panel detectors to capture and digitize the image. Differences in devices do not alter the intended diagnostic effect.

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 similar to those previously cleared in the DR 800 with MUSICA Dynamic (K180589) and other devices in Agfa's radiography portfolio today which includes DR 600 (K152639) and DR 400 (K141192). The addition of the tomographic image processing is similar to the predicate device (K132261).

Agfa's DR 800 with Tomosynthesis has an Indications For Use statement virtually identical to the predicate device (K180589) except it includes the addition of tomosynthesis. Intended uses are the same. The devices have the same technological characteristics.

The DR 800 indications for use is equivalent to the primary predicate (K132261) because both include the delineation of anatomical areas and imaging applications and application of tomosynthesis. The DR 800 and both predicate devices (K180589 & K132261) include the statement that the device is not indicated for mammography.

Descriptive characteristics and performance data including image quality evaluations by qualified radiologists are adequate to ensure equivalence. Differences in devices do not alter the intended therapeutic/diagnostic effect.

Table 1 on the next page summarizes the similarities and differences between the new device and predicate.

	DR 800 Tomosynthesis (NEW DEVICE) Agfa	**Discovery XR656 Volume RAD (PRIMARY PREDICATE - K132261) GE Medical Systems**	**DR 800 MUSICA Dynamic (REFERENCE PREDICATE–K180589) Agfa**
Communications	Same as both predicates	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 predicate K180589	40.4 cm x 40.4 cm	17x17 in. 14 x 17 in 10 x 10 in
Field Sizes	Same as predicate K180589	41 x 41 cm 35 x 41 cm 24 x 30 cm 18 x 24 cm	43 x 43 cm 30 x 30 cm 20 x 20 cm 15 x 15 cm
Pixel Size	Same as predicate K180589	200 μm	148 μm
Dynamic Range	Same as predicate K180589	14 bit	16 bit
Matrix Size	Same as predicate K180589	2022 x 2022	Static – 2880 x 2880 Dynamic – 1024 x 1024
Power Supply	Same as both predicates	50-60 Hz 100-240V auto ranging	50-60 Hz 100-240V auto ranging
Operator Workstation	Same as predicate K180589	Diagnostic Workstation	Agfa NX
Image processing	MUSICA Dynamic, MUSICA^2 MUSICA3/3+ MUSICA DTS	VolumeRAD, Dual Energy, Tissue Equalization, Auto Image Paste	MUSICA Dynamic, MUSICA^2 MUSICA3/3+
Tabletop Features	Same as predicate K180589	Tilt +/- 90° 225 x 89 cm 220kg - 320 kg maximum weight	Tilt +/- 90° 240 x 80 cm 265 kg maximum weight
Generators	Same as both predicates	Choice of three models: 50, 65KW, 80 KW	Choice of three models: 50, 65KW, 80 KW
Operating System	Same as both predicates	Windows 7, 8, 8.1, 10	Windows 7, 8, 8.1, 10
Display System	Same as predicate K180589	Separately cleared medical display	Separately cleared medical display (K051901)

Indications for Use Statements	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.	The Discovery XR656 is intended to generate digital radiographic images of the skull, spinal column, chest, abdomen, extremities, and other body parts in patients of all ages. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position and is intended for use in all routine radiography exams. When the VolumeRAD option is included on the system, the system can generate tomographic images of human anatomy including the skull, spinal column, chest, abdomen, extremities, and other body parts in patients of all ages. VolumeRAD can also be used to detect lung nodules for patients undergoing thoracic imaging. VolumeRAD generates diagnostic images of the chest that aid the radiologist in achieving superior detectability of lung nodule versus posterior-anterior and left lateral views of the chest, at a comparable radiation level. This device is not intended for mammographic 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. The DR 800 is not intended for mammography applications.

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 employed by the sponsor and independent radiologists 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

Clinical 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 800 with Tomosynthesis 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 CR&T documentation and verified. All mitigations have been tested and passed. All design input requirements have been tests and passed. All planned verification activities have been successfully completed.

- Usability and functionality evaluations were conducted with qualified independent radiographers and internal experts. The results of these tests fell within the acceptance criteria for the DR 800 X-ray system therefore, the DR 800 supports a radiographic, fluoroscopic, and tomosynthesis workflow including dynamic and static imaging, continuous and rapid sequence exams, tomographic slices calibration, and positioning.

- Image Quality Validation testing was conducted using anthropomorphic phantoms and evaluated by qualified independent radiographers and internal experts. The image quality validation included testing a full range of applications for the DR 800 X-ray system with Tomosynthesis compared to reference images from primary predicate GE Discovery XR656 with VolumeRAD (K132261) using anonymized adult and pediatric phantoms. The pediatric phantom image quality validation testing analyzed five tomographic slices at 5x the dose and five tomographic slices at 10x the dose. Both the 5x the dose and 10x the dose images are clinically sufficient and within the intended use. The test results indicated that the reconstruction software of the image processing for Digital TomoSynthesis (DTS) of the DR 800 X-ray system passed the acceptance criteria and that the DR 800 with Tomosynthesis is capable of making DTS studies for both adult and pediatric patients. The test results showed MUSICA Digital TomoSynthesis (DTS) images were suitable for diagnosis 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.

For the NX4.x.21 (NX Mentor) there are a total of 322 risks in the broadly acceptable region and 27 risks in the ALARP region with only eight 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 800 and also includes separate risk assessments for the NX4.x.21 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 800 and NX4.x.21 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: 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 60601-2-54: 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 800 with Tomosynthesis is compliant to the FDA Subchapter J mandated performance standard 21 CFR 1020.30 – 1020.32.

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 13485:2003 Medical Devices - Quality Management Systems
- ISO 14971:2012 Application of Risk Management to Medical Devices
- IEC 62304:2006 Medical Device Software – Software life cycle processes
- IEC 62366:2007 Medical Devices – Application of Usability Engineering
- 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 800 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 1999)
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (October 2014)
- 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 800 is found to have a safety and effectiveness profile that is similar to the predicate devices.

VIII. CONCLUSIONS

Agfa's DR 800 has indications for use that is consistent with those of the legally marketed predicate devices (K132261 and K180589). Intended uses are the same. Where technological characteristics differ lab tests concluded that the device is substantially equivalent to the predicates in that it does not alter the intended therapeutic/diagnostic effect.

The new device and the Discovery XR656 with VolumeRAD primary predicate device (K132261) are tomographic x-ray systems Product Code IZF. The DR 800 with Tomosynthesis also has product code JAA which is identical the Agfa DR 800 with MUSICA Dymanic predicate device (K180589). Agfa's DR 800 with Tomosynthesis is substantially equivalent to both predicate devices (K132261 & K180589) 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.